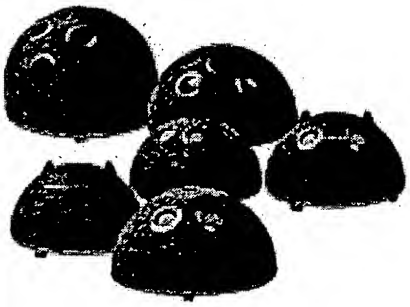
Sulzer Orthopedics
Joint Care / Fracture Care

Converge™ Porous Acetabular System
Surgical Technique

Converge™ Porous Acetabular System

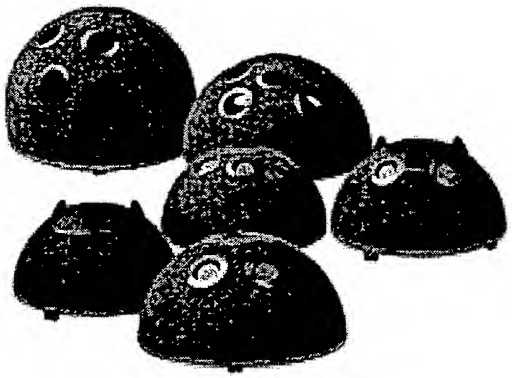


SULZER*MEDICA*

Sulzer Orthopedics

Converge Porous Acetabular System

Converge™ is a comprehensive Acetabular System designed to accommodate virtually every press-fit primary to revision situation.



Multiple Tribological Options

- Durasul™ System with highly crosslinked polyethylene.
- Metasul® metal-on-metal articulation.
- Conventional PE.

Complete Range of Liner and Cup Styles

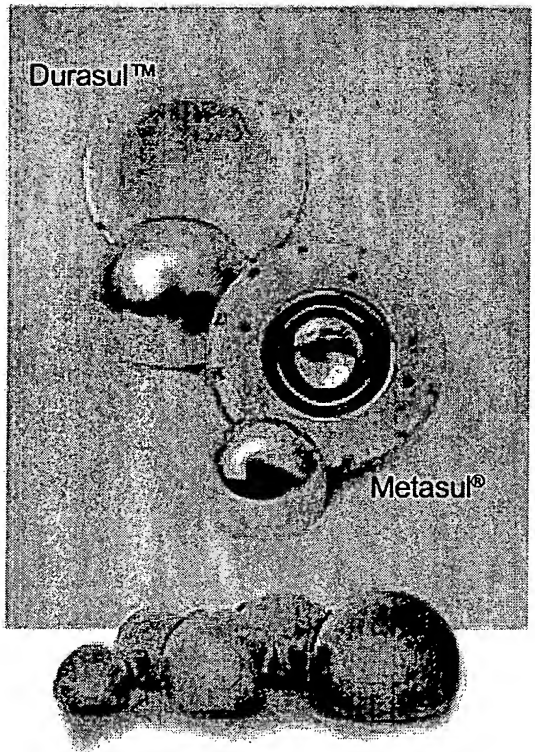
- Hemispherical, cluster-hole, rim flare with screwholes, rim flare, multi-hole and protrusio cups.
- Standard, hooded and protrusio liners.

Proven Concept for Biological Fixation

- Building on 15 years of successful results with Cancellous-Structured Titanium™ (CSTi™) coated shells, the Converge System offers enhanced bearing technologies specifically designed to address wear-related complications in total hip replacement.
- Superior industry leading liner/shell congruency.
- Excellent locking mechanism.
- Screwholes and dome hole can be sealed.
- Easy-to-use instrumentation.

Enhanced stability and range-of-motion

- Industry-first Large Diameter Head System offering 28, 32, 38 and 44mm CoCr heads in combination with Durasul PE.
- Chamfered liner geometry.



22, 28, 32, 35, 44mm CoCr Heads

Sulzer Orthopedics

Converge Porous Acetabular System

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Templating the Acetabulum

Unlike the femur, the acetabulum is templated using the side to be reconstructed. Estimation of the size of the acetabular component is the primary objective of templating the acetabulum. Proper size determination helps in selecting the proper reamers and evaluating the coverage of the cup. Large defects present on the operative side must be taken into account. In the majority of cases, an approximate size can be determined.

The acetabulum is templated on both the A/P and lateral radiographs. The hemisphere of the acetabular component is aligned with the mouth of the bony acetabulum, avoiding any osteophytes. On the A/P radiograph (Figures 1 and 2), the component should rest on the cortical floor of the cotyloid notch, and may touch but should rarely violate the teardrop or the ilioischial line (Kohler's line); the component should have a maximum lateral opening of 40 degrees. If protrusio is present, the lateral edge of the teardrop is used. The cup size selected may appear to remove excessive iliac bone on the A/P radiograph, but the lateral film gives a better indication of cup size since the hemispherical subchondral bone can be clearly seen. On the groin lateral radiograph, the cup size selected should contact the anterior and posterior rim of the bony acetabulum and the medial subchondral bone. The center of rotation of the femoral head should be anatomically reproduced by the position of the acetabular component.

If a bony defect is identified, use the correctly placed template to measure for size and determine any need for bone graft.

Figure 1

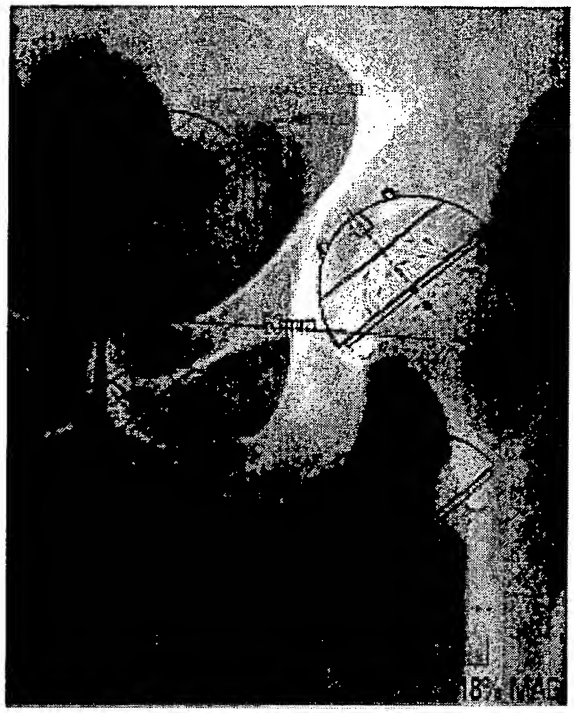
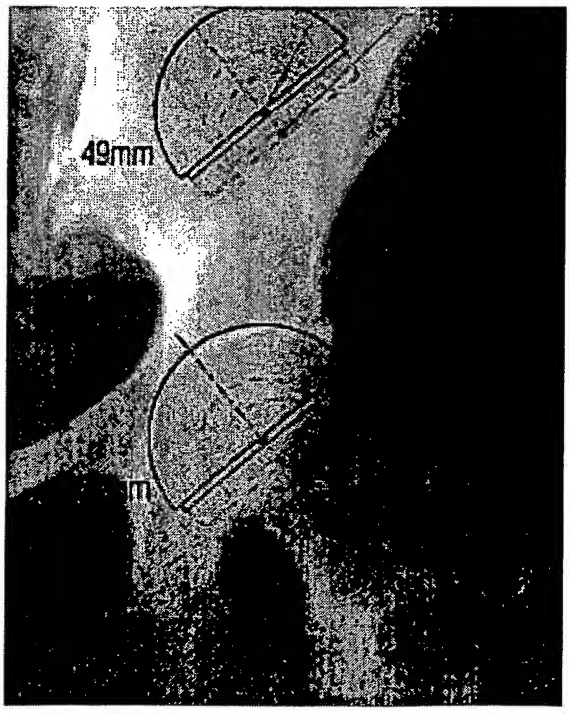


Figure 2



Joint Exposure

Posterior lateral approach
The straight, longitudinal portion of the incision begins four fingerbreadths below the vastus tubercle and continues to one fingerbreadth above the tip of the greater trochanter. It then curves toward the posterior inferior spine, or 60 degrees to the straight line of the incision (Figure 3).

The incision is carried sharply down through subcutaneous tissue, fascia lata and the fascia of the gluteus maximus muscle. This muscle is gently split in line with its fibers. A self-retaining Charnley retractor is applied.

To retract the gluteus medius superiorly and reveal the piriformis tendon, either a 9/64-inch Steinmann pin or a small bent Hohman retractor should be placed under the gluteus medius and on top of the gluteus minimus. The femoral insertion of the gluteus maximus tendon is transected one centimeter from its insertion to permit easy retraction of the femur anteriorly and to allow complete visualization of the acetabulum.

If desired, a leg length measurement can be taken at this time. With the hip in 30 degrees of flexion, neutral rotation and neutral abduction/adduction, the distance is measured between the superior pin and a drill hole placed in the greater trochanter.

The knee is flexed, and the leg is internally rotated. Using a hot knife, the piriformis, short external rotators, quadratus femoris and posterior capsule are incised off the posterior trochanter as a continuous sleeve to expose the lesser trochanter (Figure 4). The hip is dislocated. A bone hook or skid may be used to avoid excess torsion on the femoral shaft.

Ordering information for implants and instruments can be found inside the back cover of this technique.

Figure 3

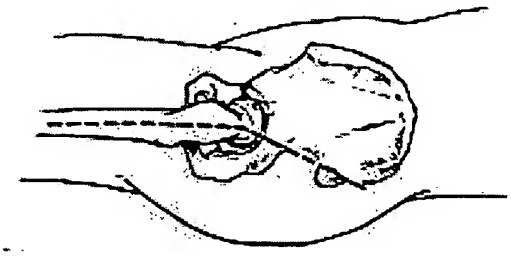
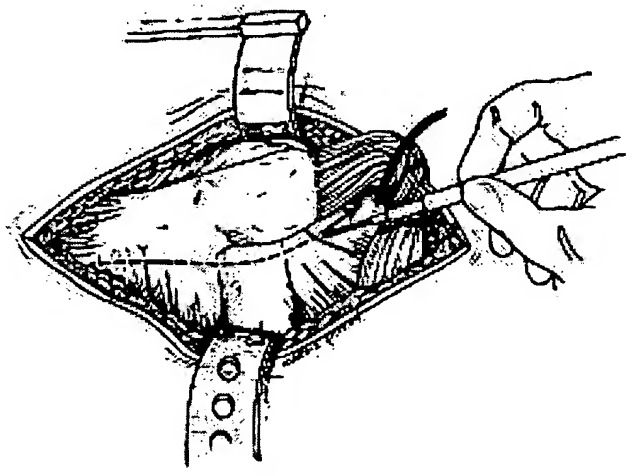


Figure 4



A Hohman retractor is placed distally to the capsule into the obturator foramen. The medial capsule is incised to the posterior insertion of the transverse acetabular ligament. Hohman retractors are placed under the lesser trochanter and femoral head for exposure of the head and neck. This permits adequate visualization for proper transection of the femoral neck (Figure 5).

Note: If bone slurry is to be placed into the acetabulum, the posterior portion of the head is "decapitated" and graft obtained with the smallest acetabular reamer prior to the osteotomy.

Transect the femoral neck at the templated level, then retract the femur anteriorly to expose the acetabulum. Move the distal Hohman retractor to a position under the neck during transection to protect the sciatic nerve.

A curved "snake" retractor is placed on the pelvis at the superior-anterior corner of the acetabulum (10 o'clock for left hip, 2 o'clock for right hip) to hold the femur anterior to the acetabulum (Figure 6). For retraction of the capsule posteriorly, either a posterior acetabulum retractor or two 9/64-inch Steinmann pins driven into the ischium and posterior column may be used. These are inserted inside the capsule but outside the labrum, thus using the capsule to retract the sciatic nerve out of harm's way. A Hohman retractor is positioned under the transverse acetabular ligament. The labrum and osteophytes are removed for exposure of the acetabulum. The entire acetabulum should now be in full view.

It may be necessary to cauterize the acetabular branch of the obturator artery as reaming begins, since it enters the acetabulum under the transverse ligament at its ischial attachment.

Figure 5

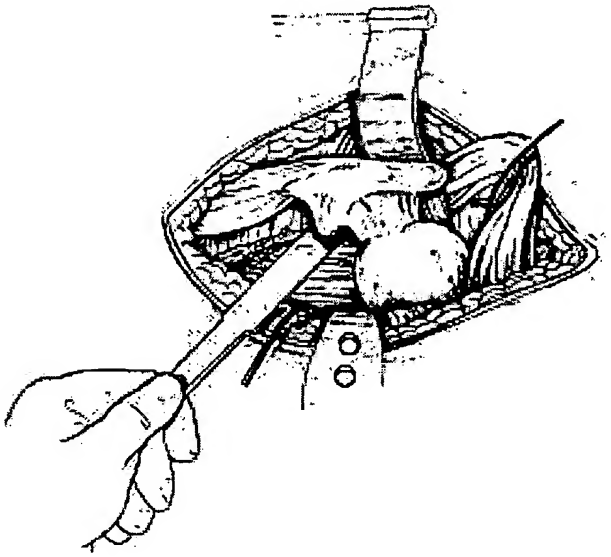
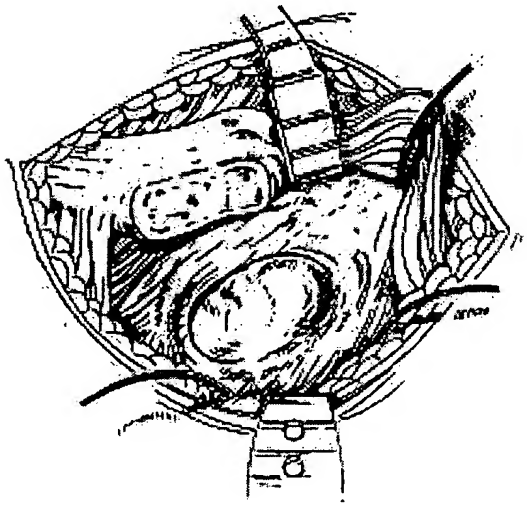


Figure 6



Joint Exposure—Alternate Approach

Anterior lateral approach
With the hip flexed about 30 degrees, a straight incision of approximately 25cm in length is made, centered over the middle of the greater trochanter. It should extend at least 10cm proximal to the tip of the greater trochanter (Figure 7).

The gluteus maximus muscle is divided in the direction of its fibers. After the gluteus maximus and tensor fascia are carefully dissected from the gluteus medius fascia, a Charnley self-retaining retractor is inserted.

The leg is positioned into neutral rotation. Using cautery, an incision is made through the mid-vastus lateralis fascia, crossing the mid-greater trochanter, then following the direction of the fibers, the gluteus medius is divided in half (Figure 8).

The gluteus medius is divided no more than 3cm proximally, so as not to potentially denervate the anterior half. The thick tendinous portion of the posterior gluteus medius should be left attached to the greater trochanter.

Figure 7

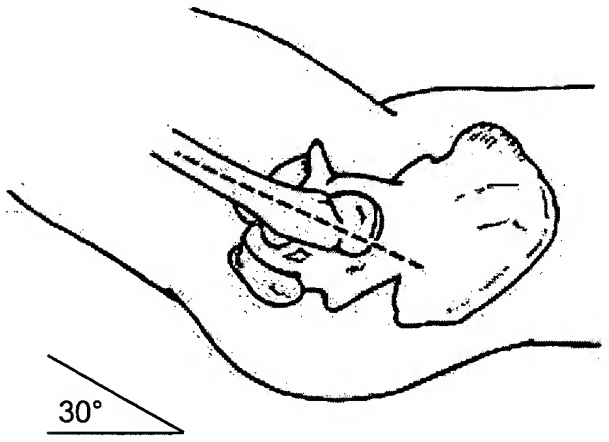
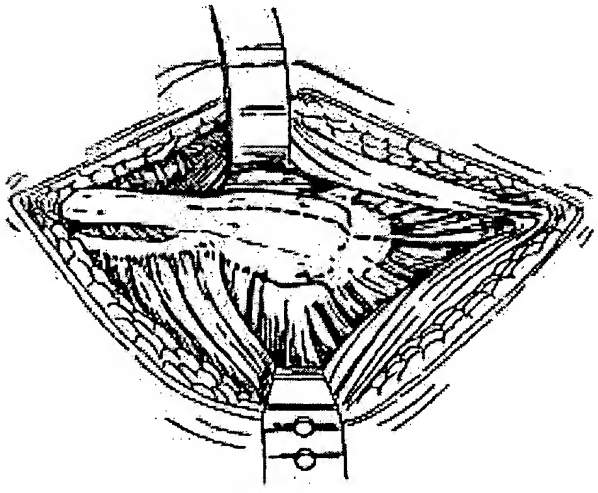


Figure 8



The anterior vastus lateralis/gluteus medius sling is released from the anterior greater trochanter with a thin piece of bone (about 2.5cm x 1cm in size), removed with a one inch wide curved Lambotte osteotome. The gluteus minimus muscle and tendon is elevated from the superior joint capsule. The gluteus minimus tendon is then elevated from the anterior lateral greater trochanter in continuity with the gluteus medius/vastus lateralis flap (Figure 9).

The rectus femoris muscle is elevated from the anterior capsule until the iliopsoas tendon/anterior capsule interval is identified. The iliopsoas tendon and rectus femoris are retracted from the anterior capsule with a cobra retractor, which is held in place by the Charnley self-retaining retractor.

The joint capsule is incised longitudinally from posterior of the top of the acetabulum to the mid lateral neck. The incision continues along the capsular insertion anteriorly to the mid anterior neck, then across to the anterior inferior iliac spine.

Charnley pins or 9/64-inch Steinmann pins are used to retract the capsule, anterior gluteus medius and gluteus minimus. One pin is inserted at 12 o'clock, 1cm above the lateral lip of the acetabulum. A second pin is inserted at either 10 o'clock for left hips or 2 o'clock for right hips, 1cm above the anterior lip of the acetabulum (Figure 10). If severe shortening is present preoperatively, the entire capsule should be excised.

Figure 9

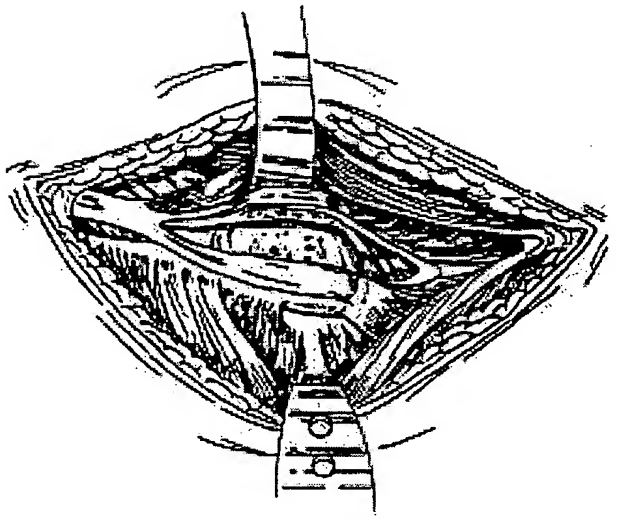
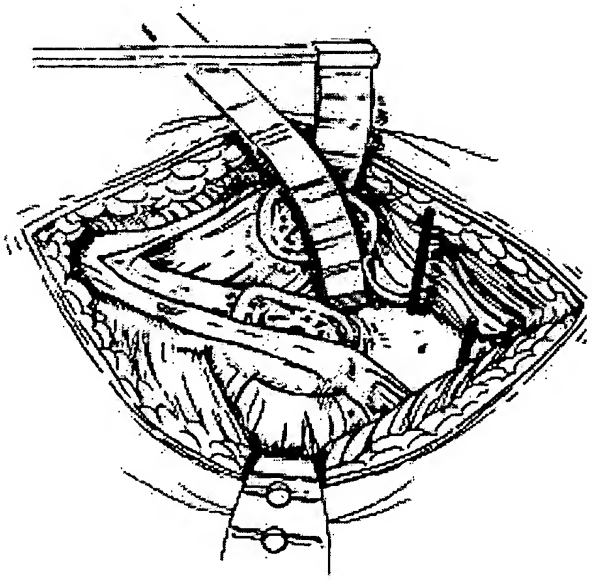


Figure 10



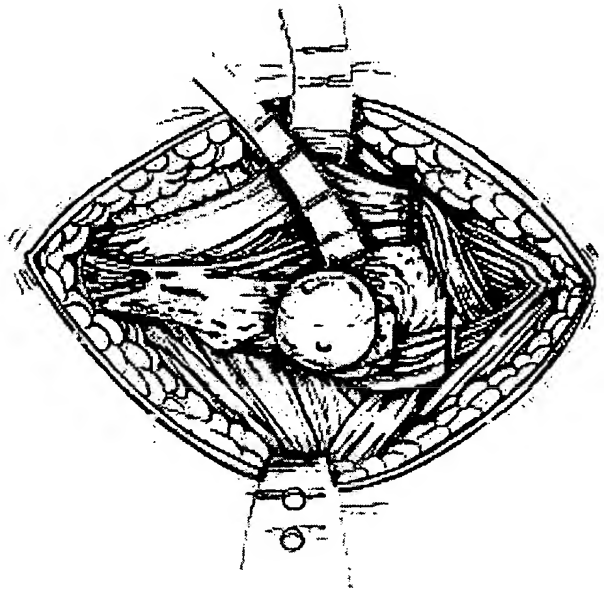
A drill bit is temporarily inserted into the distal greater trochanter. With the hip in 30 degrees of flexion, neutral rotation and neutral abduction/adduction, the distance is measured between the drill bit and the superior pin for later confirmation of leg lengthening.

The hip is dislocated anteriorly via traction in extension, adduction and external rotation (Figure 11), and the leg is placed in a sterile bag off the edge of the table.

The offset measurement (i.e., center of femoral head to tip of greater trochanter) is obtained.

Note: The remainder of the surgical technique is illustrated from a posterior lateral approach.

Figure 11



Acetabular Preparation

Reaming of the acetabulum should begin with a reamer that is two sizes smaller than the preoperatively selected acetabular component size. By using reamers two sizes smaller, the fit of the reamer does not exceed the anterior-posterior diameter, but it is not so small that excessive reaming either anteriorly or posteriorly will occur. By using reamers which are sized too small, the threat of reaming either preferentially anteriorly or posteriorly is present and this can create more of an ellipse than a hemisphere which makes fit of the acetabular component more difficult.

Reaming begins transversely toward the cotyloid notch. The ridges of the "horseshoe" (or medial osteophytes) should be removed. Reaming then proceeds in the position of desired anteversion, creating a hemisphere (Figure 12). Larger reamers are used until the anterior and posterior rim of the acetabulum is contacted. The reamer should not be sunk below the superior rim of the bony acetabulum or reamed through the cortical bone of the cotyloid notch. Cancellous bone will be evident where the horseshoe ridges have been removed. Bleeding subchondral bone is left superiorly at the dome.

All osteophytes are removed to palpate the true acetabular rim during implantation of the cup. The proper size shell trial is selected according to reamer size. Shell trials are available in even sizes only. The shell aligner/positioner keys off the dome of the shell trial and is threaded into place. This shell aligner offers anteversion and abduction references as well as rotational control. The aligner features a teardrop shape that mates with both the shell trials and the implants in only one orientation (Figure 13). It is recommended to assemble the aligner to the shell trial by keeping the trial concave side up as provided in the instrument case. Then simply key the teardrop on the aligner to the apex of the shell trial and push down while threading into place.

Note: For consistency, the implants are packaged concave side up as well and can be mated with the aligner in the same manner as the shell trials.

If no alignment features are desired, the straight threaded rod may be used as a second option with the shell trials. It simply threads into the dome of the shell trial until the shoulder above the threads makes contact with the shell trial.

Figure 12

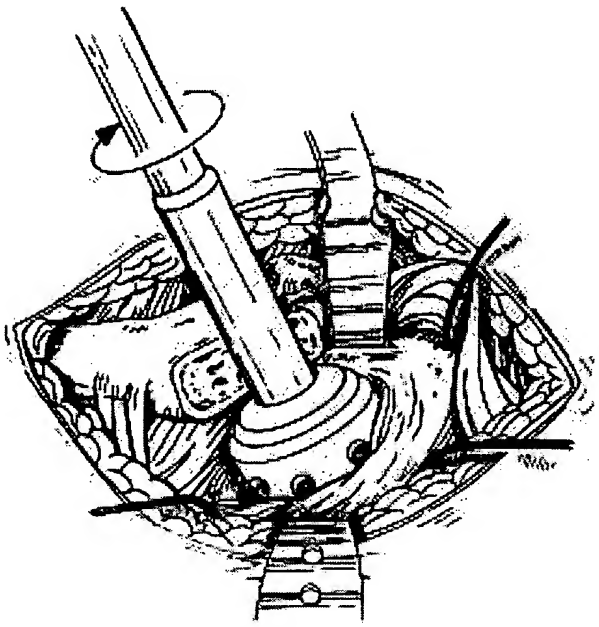
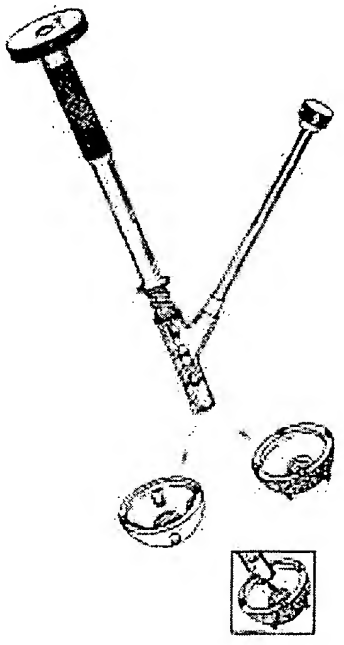


Figure 13



WARNING: All threaded instruments must be tightened onto the components until completely seated. If they are not tightly threaded, the load from impaction will be transferred to the threads and possible damage to the threads will occur.

After the shell trial is inserted into the acetabulum, its seated position is verified through the trial windows. The edge of the shell trial should lie level with the anterior-inferior margins of the acetabulum and should completely fill the anterior-posterior bony acetabulum. The trial should be stable to manual testing. If the trial is not stable, the next larger size should be used. If too tight, the rim of the bony acetabulum is reamed with the next larger size grater.

The shell trial must be stable prior to selecting that size acetabular component.

The proper size shell trial and insert trial are placed. The trial insert can be held by placing an instrument in the holes located on the rim (Figure 14), and then placed inside the shell trial. The insert trials contain a captured screw at the apex and can be threaded into the dome of the shell trial or implant with the straight hex head screwdriver (Figure 15). Warning: The captured screw is intended only to hold the trial insert in place and does not need to be overly tightened. Breakage can occur with excess torque on the captured screw, but the trial insert would still be functional.

After trialing, the proper size acetabular shell may be implanted or the trials left for articulation with the femoral trial.

Note: The appropriate implant labeled 1 size larger than the final shell trial should be used.

Example:

Shell	Final Reamer Size (mm)	Final Shell Trial Size (mm)	Implant Label Size (mm)	Actual Shell OD (mm)	Press-Fit (mm)
Hemispherical	52/51	52	53	53.0	1.0/2.0
Cluster-Hole	52	52	53	53.5	1.5
Rim Flare	52	52	53	53.5	1.5
Rim Flare with screwholes	52	52	53	53.5	1.5
Multi-Hole	52	52	53	53.5	1.5
Protrusio	52	52	53	53.5	1.5

Figure 14

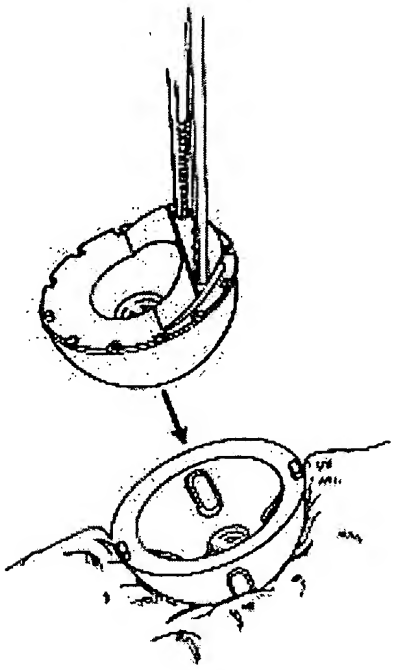
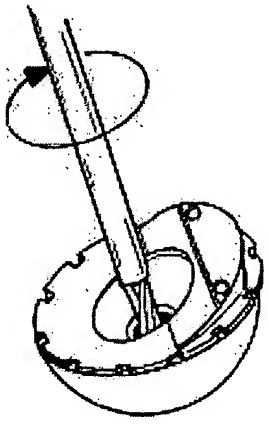


Figure 15



Acetabular Implantation

Shell Placement for Cluster-Hole and Hemispherical Shells

The acetabular shell is positioned into the acetabulum using the same acetabular shell aligner/positioner used with the shell trials. A second option would be to use the straight threaded rod if no alignment features are desired, taking care to seat the threads of the straight rod completely. The cup is positioned in 20 degrees to 25 degrees of anteversion, with an abduction angle of 35 degrees to 45 degrees. The aligner/positioner provides a 40 degree abduction angle when the vertical rod of the holder is held "straight up and down," or at 90 degrees to the body (Figure 16). Remember that the X-ray position of the cup is often 5 degrees to 10 degrees more vertical than estimated intraoperatively, so err toward more horizontal. To determine anteversion, the 3/16-inch alignment rod is inserted into one of the holes in the shell aligner for either a left or right hip and rotated until it is aligned with the mid or posterior shoulder, providing 20 to 25 degrees of anteversion (Figure 17).

Note: To use the shoulder as a reference, the trunk must be stabilized by holders. If the shoulders slump forward, as happens with a "bean bag," this technique is not accurate.

The anatomy of the acetabulum may also be used to assure the correct position of the acetabular shell. If there is no bony deformity such as dysplasia, the edge of the cup should not be allowed to sink below the superior margin of the true acetabulum. The anterior-inferior medial edge of the acetabulum, which is the junction of the anterior rim (pubic tubercle) with the transverse ligament should be identified. In an acetabulum without deformity, there will be a distinct rounded prominence. The acetabular shell should be 5mm below this tubercle and should be flush with the medial edge of the cotyloid notch or at the level of the transverse acetabular ligament.

Figure 16

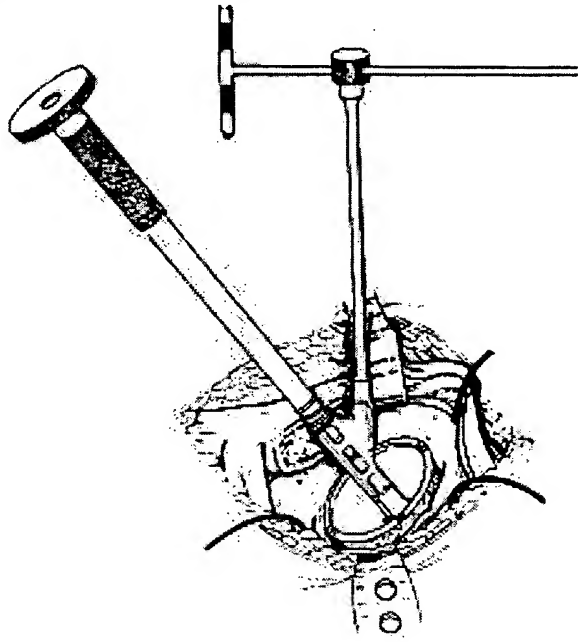
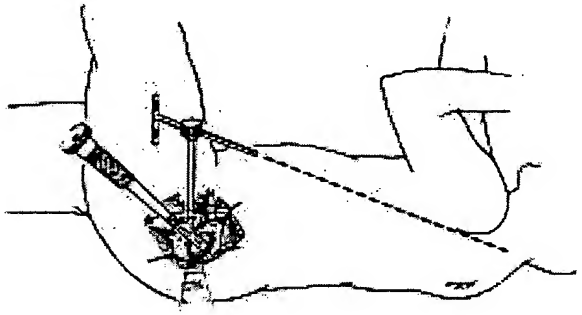


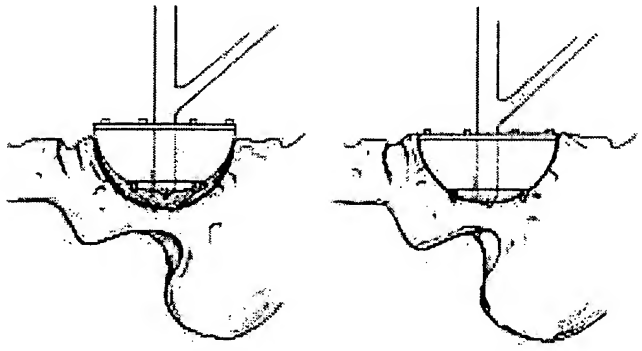
Figure 17



Shell Placement for Rim Flare Shells
After achieving proper fit and stability of the shell trial, it is removed and preparations are made to implant the rim flare shell. In primary THA situations, cancellous bone slurry is placed within the acetabulum to fill any bone cysts as well as to provide for approximately a 1mm interface layer. The rim flare shell, assembled to the aligner/positioner or the straight threaded rod, is then partially inserted until the rim begins to engage, taking care to avoid engaging the spikes into the acetabular bone (Figure 18A). The implant is then positioned into proper abduction and anteversion prior to being impacted into its final position. After impaction, the spikes will engage centrally into cancellous bone, greatly improving stability (Figure 18B). Enough stability should be present to move the entire pelvis with the shell holder.

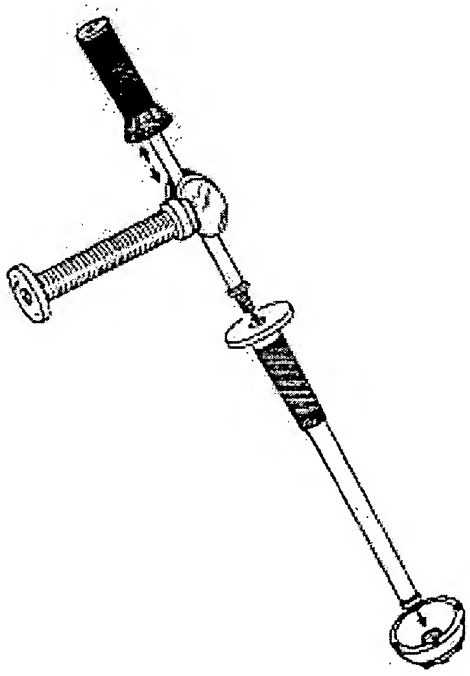
Note: Do not attempt to rotate the rim flare shell once the spikes have been seated. If a direct axial extraction method is needed, use the universal extractor slaphammer with the universal impactor handle assembled to the straight threaded rod. An upward sliding motion to the backside of the impactor handle will effectively extract the implant axially (Figure 19).

Figure 18



A. Posterior view B. Posterior view

Figure 19



Optional Screw Placement
If a shell with sealed screw holes is chosen for implantation, it is assembled to the aligner/positioner in the same manner as the shell trials. The straight threaded rod may also be used here if no alignment features are desired.

After the shell has been positioned and seated correctly (as described in the rim flare shell section) within the acetabulum, one or more of the removable screw hole seals may be extracted with the provided instrument. This is accomplished by inserting the end of the screw hole seal extractor into the indention of the screw hole seal (Figure 20). Using a "lever-out" motion, the screw hole seal will dislodge with moderate force (Figure 21).

Note: Take caution not to scratch the inner diameter of the shell with the extractor or screw hole seal upon removal. Once a screw hole seal has been removed, it can not be reinstalled. Screw hole seals may be extracted at the back table if preferred.

Note: All shells are provided with a titanium dome plug. Be sure to install the dome plug to all shells with the straight hex head screwdriver prior to impaction of insert. Once the dome plug is installed, trial inserts cannot be used without removing the dome plug. (See Figure 56 on page 33.)

Figure 20

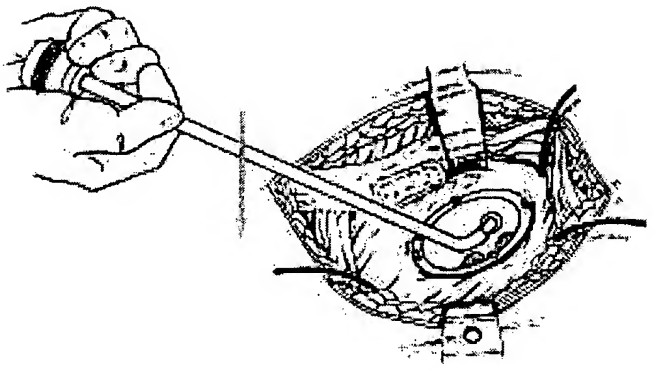
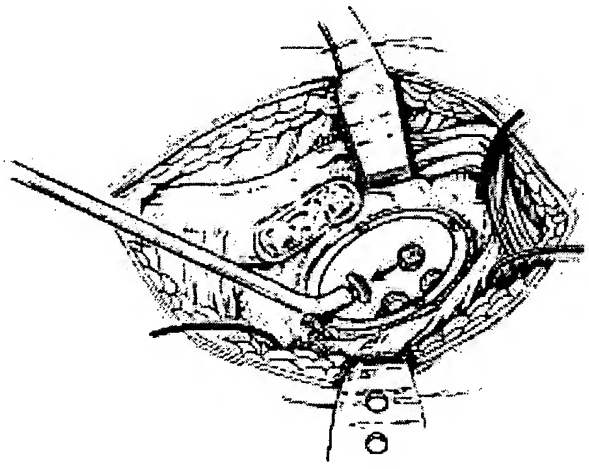


Figure 21



A 3.2mm or a 4.5mm drill bit connected to the flexible driver (or optional fixed angle driver without the drill guide) is inserted through the drill guide.

The drill guide and the chosen drill bit are positioned into the selected screw hole at an angle up to 16 degrees in any direction, and the hole drilled (Figure 22). A finger should be used to protect the sciatic nerve and superior gluteal artery during drilling of the iliac holes. The depth gauge is inserted into the drilled holes to permit selection of the proper length bone screw. The depth can be read in the window of the depth gauge (Figure 23).

Figure 22

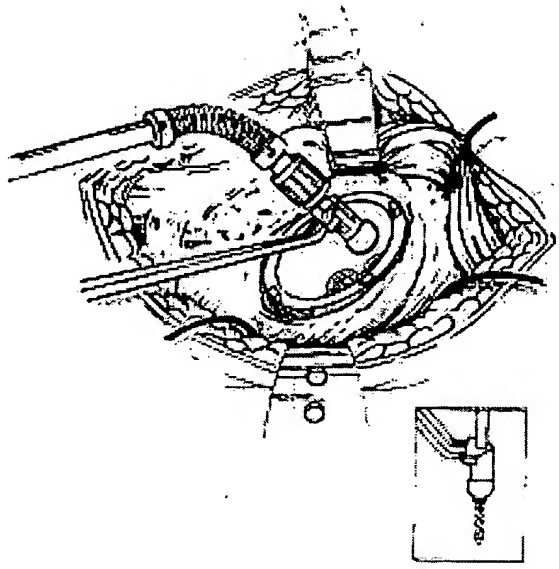
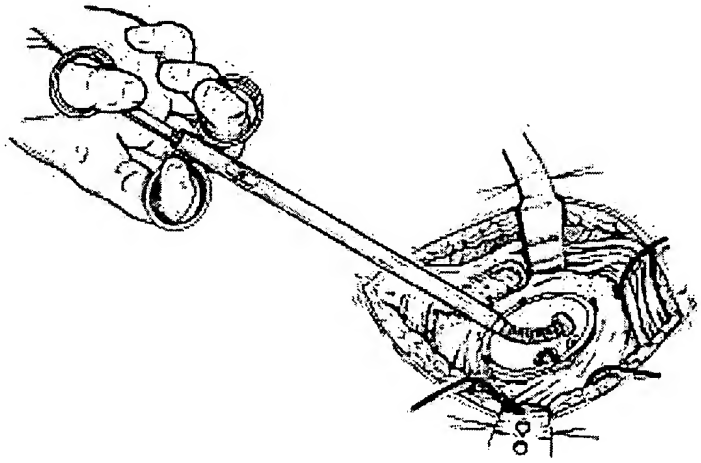


Figure 23



If needed, a 6.5mm tap bit is available for use with the flexible driver assembled to the ratchet handle or fixed angle driver (Figure 24). The bone screw is seated into the hole using the U-joint screwdriver (Figure 25). **Note**: Use moderate pressure to secure the bone screw onto the twisted hex driver.

Up to two holes can be drilled into the ilium and screws seated in this manner. **Note:** Optimal fixation has been achieved when the screws display a solid grip and do not spin. No screw should be more than 50mm in length. It is imperative that all the bone screws be completely seated into the countersunk holes of the shell to allow the acetabular insert to snap into place properly (Figure 26).

Also, please note that if screws are used they may pull the shell more vertically, closer to 45 degrees. If screw placement moves the cup position more than 5 degrees in any plane, the shell is too small. Only Sulzer Orthopedics 6.5mm cancellous bone screws should be used.

WARNING: Sulzer Orthopedics bone screws are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Figure 24

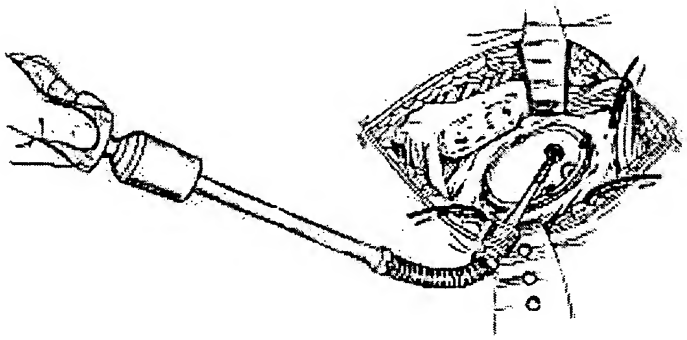


Figure 25

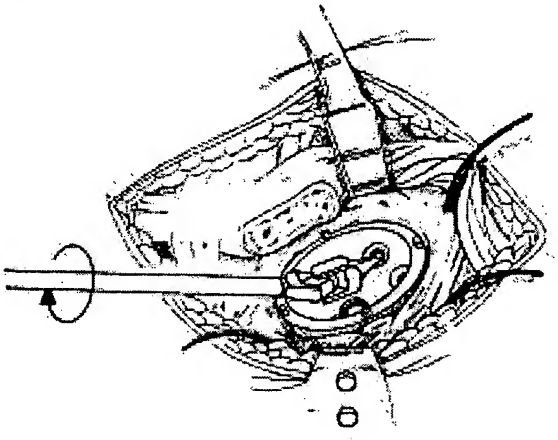
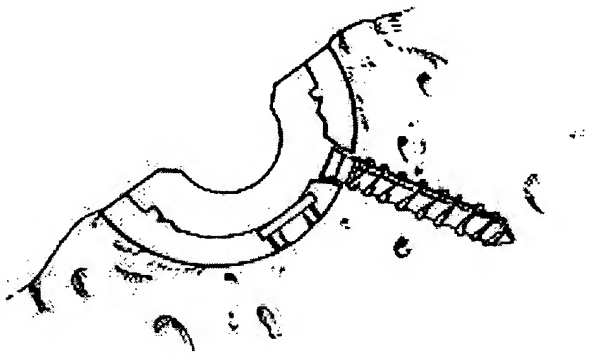


Figure 26



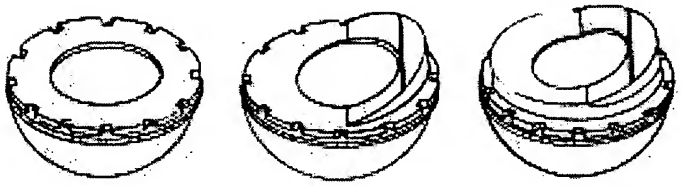
Polyethylene Insert Placement

Standard, hooded and hooded protrusio inserts are available to provide maximum surgical latitude at the time of surgery (Figure 27). The appropriate style and size insert is selected and its rim slot configuration lined up with the antirotation pegs on the shell (Figure 28). Either a rim loaded or inner diameter loaded insert impactor may be selected for impaction of the insert into the shell (Figure 29).

Note: A hooded protrusio liner is used when the shell is purposely placed proximally or medially to reestablish the normal hip anatomic center, or when additional hip length (i.e., more than what is available with the +8mm head/neck segment) is needed for stability. The Converge protrusio inserts provide an additional 6mm of polyethylene at the dome of the insert for lateralization of the center of rotation.

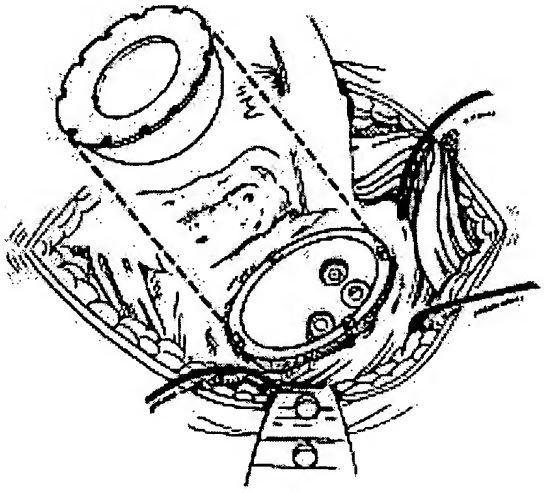
Note: The rim impactor is reversible for either a standard insert or a hooded insert. The correct surface should be face down for proper mating with the chosen insert (Figure 29).

Figure 27



Standard insert | Hooded insert | Protrusio insert

Figure 28



The chosen impactor is assembled, until the threads are completely seated, to an impactor handle also provided (Figure 29). A mallet should be used to seat the insert into the shell properly. The insert's flange-to-shell face contact indicates complete assembly.

Note: To guarantee proper impaction of the inserts, special rim loaded insert impactors are required for the smaller Durasul inserts. For proper selection of the right rim impactor, please refer to the instrument list at the end of the surgical technique.

Note: All inserts should require two to three moderate impaction blows with a surgical mallot.

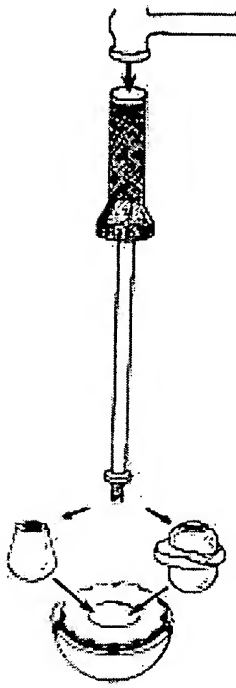
If the insert should require removal after being snapped into place, an insert extractor is provided that can be assembled to the ratchet handle and AO adapter. Drill a hole with a 4.5mm drill bit through the insert off-center at least 5mm from the dome hole and as vertical to the shell face as possible. Then manually drive the insert extractor threads into the prepared hole and extract the insert (Figure 30).

Note: Clean and remove any positive burrs or material that could possibly be created by the extractor.

For insertion and removal of a Metasul liner, see pages 18-23.

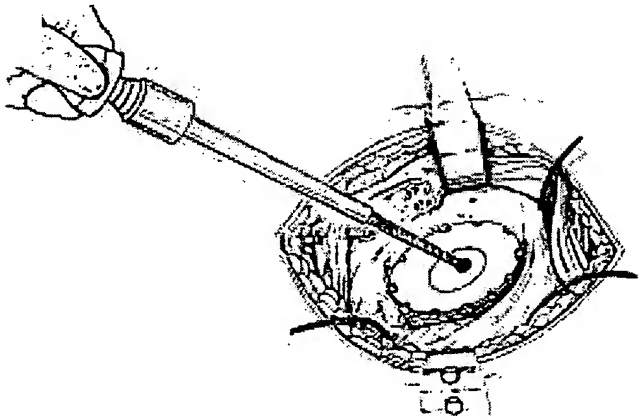
For femoral preparation, please refer to the appropriate Sulzer Orthopedics surgical technique.

Figure 29



Rim impactor is reversible

Figure 30



Metasul Usage Keys

A Metasul inlay must only be used with a Sulzer Orthopedics Metasul head. The Metasul components are precisely coordinated with one another with regard to surface quality, tolerance of clearance, and choice of materials.

A Metasul head must never be attached with a stem from another manufacturer. There are up to 30 different types of tapers on the market, and the differences are not always apparent to the naked eye. Thus, fretting, corrosion, and possibly destructive failure can occur with mixed couples.

Note: If the surgeon nevertheless matches components of different manufacturers, he legally becomes the manufacturer of the implant system. Thus, he is also liable in the event of complications.

Contraindications

The nonhooded Metasul should not be used in patients where a hooded or constrained liner are necessary for joint stability. Metasul should not be used in a hip joint to revise a failed or fractured ceramic implant. Ceramic particles, though safe, are extremely destructive to the Metasul interface.

The Metasul acetabular liner cannot be used with any shell other than the designated Sulzer Orthopedics Converge shell, nor with any other head than a Sulzer Orthopedics Metasul femoral head. Metasul liners can not be used with other Sulzer Orthopedics CoCr or ceramic femoral heads.

The utilization of the Metasul product will be very similar to the procedure for the 28mm (standard nonhooded) polyethylene liner. Standard operative procedures for the shell and liner should be used.

Additional important information is included in this surgical technique regarding Metasul usage, contraindications, placement and removal protocols. Please read the Converge methods in the previous section for specific instructions for shell placement. This document is to serve as an aid for the surgeon using Metasul with the Converge Porous Acetabular System.

Metasul Insert Placement

Metasul is available only in a standard, nonhooded, 28mm inner diameter design. It is recommended that a trial reduction, using a nonhooded trail liner, be performed for all Metasul surgeries. For surgeons who routinely use a hooded inserted, and/or a 32mm head, this is even more important to ensure joint stability and avoidance of dislocation.

The best technique to ensure that the anteversion of the cup and stem are mated correctly is to observe the symmetry of the femoral head in the trial liner with the hip flexed to 30 degrees and internally rotated 10 degrees. In this position, the head should appear symmetric within the trial liner. A second test is that throughout the entire range of motion of the hip there should not be more than 50% of the head uncovered in any position. If the head and cup are mated in this manner, the occurence of dislocation would not exist because of the anteversion of the cup and/or stem.

The specific Metasul impactor is selected, and is threaded onto the impactor handle (Figure 31). A mallet will be used to seat the insert into the shell. The insert's flange-to-shell face contact indicates complete assembly.

Note: All inserts should require two to three moderate impaction blows with a surgical mallet.

Figure 31

Liner Removal

If the insert should require removal after being snapped into place, an insert extractor is provided (Figure 32). The device is oriented as shown, for placement into the liner and shell (Figure 33).

The point at the end of the T-handle is then placed into one of the 12 slots around the periphery of the shell. The round plate at the base of the extractor is placed into the inner diameter of the Metasul liner (Figure 34).

Figure 32

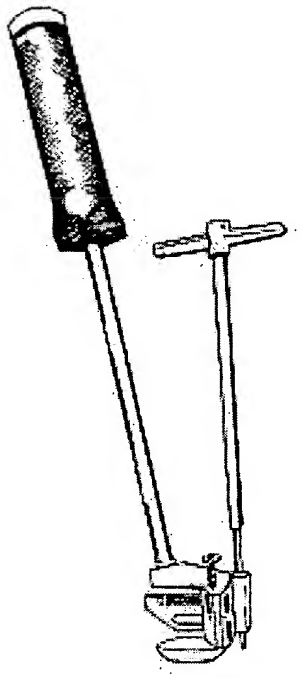


Figure 33

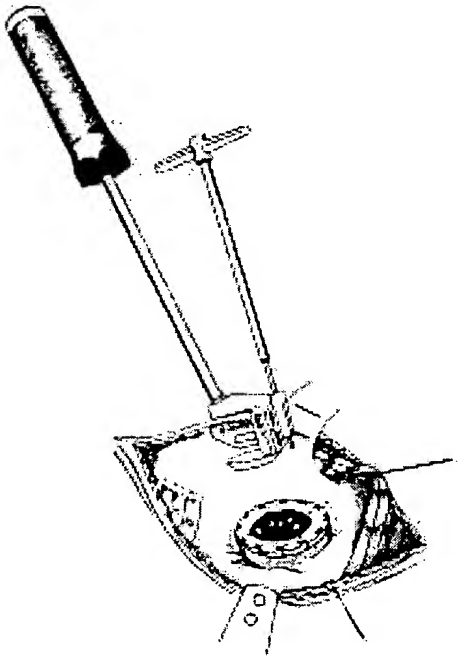
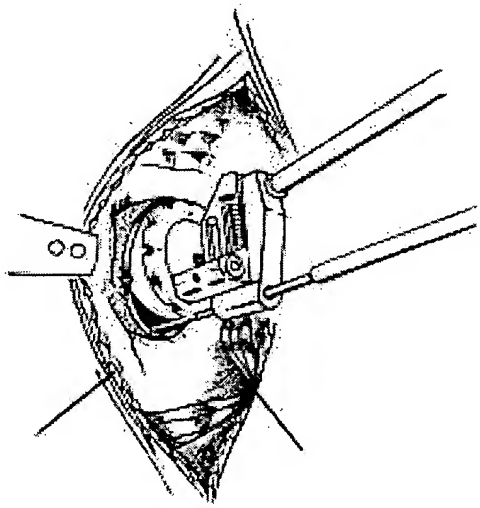


Figure 34



A hexhead screwdriver is then placed into one of the screws near the body of the extractor. A light tap from a small hammer to the screwdriver is used to initiate engagement of the screw into the polyethylene (Figure 35). The screw is then manually advanced using a clockwise motion until fully seated. This technique is then repeated with the screw on the opposing side (Figure 36).

Note: The use of a standard AO hexhead screwdriver is recommended for use with the removal device. The twisted hex screwdriver provided will function, but binding of the screwdriver may occur in the screw holes. If this occurs, gentle torsional and extractive pressure will remove the screwdriver.

Figure 35

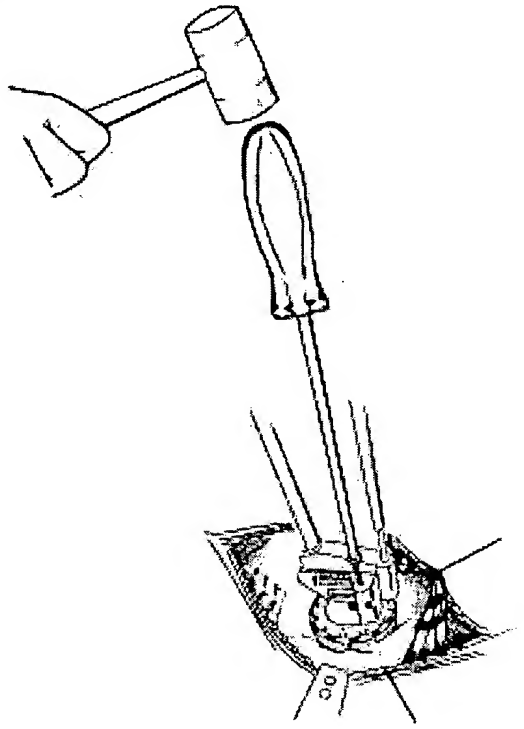
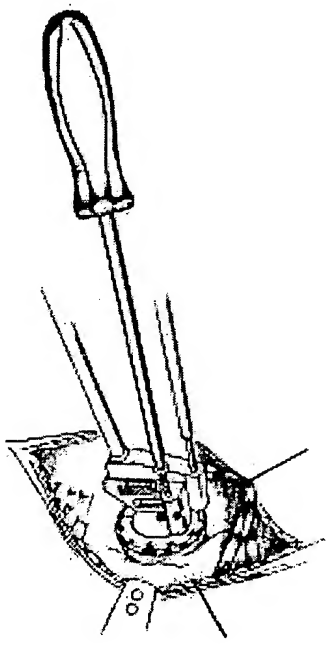


Figure 36



When both scews are seated, the T-handle on the extractor may be turned in a clockwise manner to create an extraction force on the liner. The liner should come away from the shell fairly easily (Figure 37).

If there is any problem in retrieving the liner, then reposition the extractor device in another orientation. This will provide a pristine portion of polyethylene to use for extraction. This extraction device also safeguards the shell from inadvertent scratching or damage from a removal tool.

Note: Once the liner is removed using this technique, it should not be reinserted or reimplanted.

Alternate Liner Removal Techniques

If an extraction device is not available, or a surgeon chooses not to use one, there are other options available for liner extraction. The liner may be removed by creating a slot in an area between the inner diameter and the outer rim.

The curved osteotome may then be placed into the slot to lever the liner away from the shell (Figure 38).

The liner may also be removed using a Midas Rex™ type of service. A circumferential trough may be cut around the Metasul liner. This will relieve pressure on the locking mechanism of the shell-liner interface. An osteotome may then be used to lever the liner out of the shell.

Note: After extraction of a Metasul liner, as with all liners, it is important to closely inspect the remaining shell for any scratches or other damage. This could create an abrasive contact between the shell and polyethylene.

Figure 37

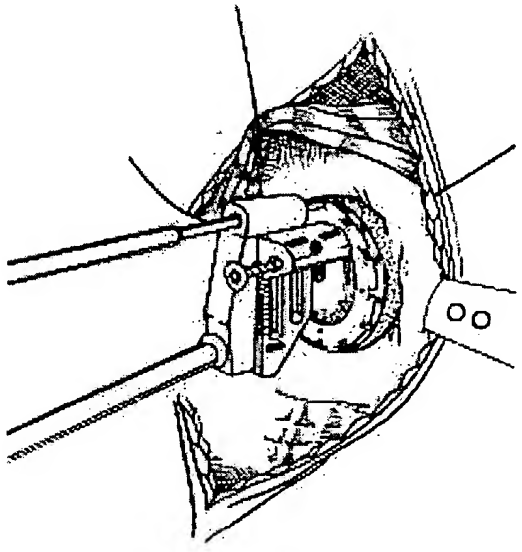
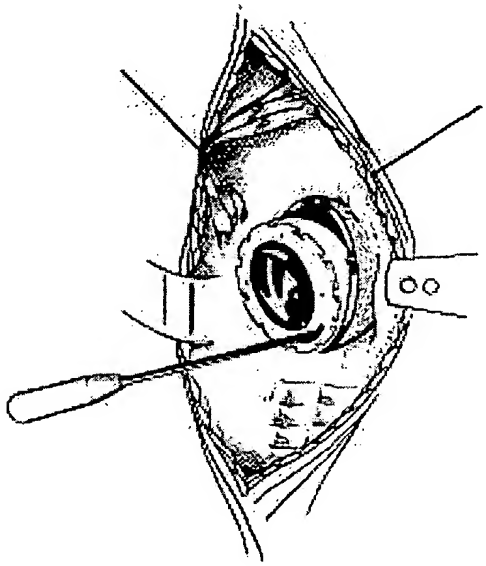


Figure 38



Revision Total Hip Joint Exposure

Multi-Hole or Protrusio Shell
The majority of revision total hip replacements can be performed utilizing the standard anterior lateral or posterior lateral soft tissue approaches to the hip described earlier in this technique. In certain cases requiring greater acetabular exposure to deal with large bony defects or greater femoral exposure to remove well-fixed cemented or cementless femoral stems, modified greater trochanteric osteotomy approaches are helpful. The traditional greater trochanteric osteotomy will certainly provide excellent acetabular exposure but should be avoided due to an unacceptable non-union rate. This is because in revision situations one frequently will have a poor trochanteric bed for reattachment due to the previous cement. Also, if shortening had occurred pre-revision, it may be difficult—once appropriate leg lengthening has been achieved—to bring the trochanter down.

A greater trochanter slide approach is an excellent alternative to the traditional trochanteric osteotomy because a thinner piece of bone is removed which improves the bone stock of the remaining trochanteric bed. Also the vastus lateralis is left attached to the distal end of the osteotomized bone. In cases where a poor bed remains for attachment or if the trochanter can not be brought back distally to the level of its old bed, part or all of the bone in the osteotomized segment can be removed. This still maintains abductor function via its continuity through the attached vastus lateralis to the femoral diaphysis.

A straight lateral incision is used with the hip flexed 30 degrees and the fascia lata is incised in the line of the incision. The vastus lateralis fascia is incised longitudinally about a centimeter anterior to the vastus intermuscular septum. The vastus lateralis muscle is elevated from the femoral diaphysis. The greater trochanter osteotomy is then made with an oscillating saw just below the anterior and posterior attachment of the gluteus medius and the proximal attachment of the vastus lateralis fascia. The external rotators and the gluteus minimus tendon is left attached to the proximal femur. The removed trochanter fragment is usually about one centimeter thick proximally and one-half centimeter thick distally. The vastus lateralis-greater trochanter-gluteus medius sleeve is retracted anteriorly.

The external rotators and gluteus minimus are sharply incised from the bone. The joint capsule is then excised. Some posterior joint capsule can be left attached to the external rotators to enhance their integrity, but is incised proximal and distal to the rotators and detached from the posterior acetabulum. The hip is then dislocated anteriorly, the hip flexed and externally rotated, and the leg placed in a sterile drape off the operating table anteriorly to expose the femur. For acetabular exposure, the limb is placed back on the table, the hip partially flexed, and the proximal femur retracted posteriorly with a sharp Hohman retractor placed in the ischium.

Once the revision of the femoral and acetabular components is complete, two wire cables are placed proximally and distally, horizontally through the anterior and posterior greater trochanter bony bed exiting the anterior and posterior cortices, then through the lesser trochanter. Four drill holes are then made in the greater trochanter for the two wire cables. The external rotators are reattached to the proximal femur with sutures placed through bone. The gluteus minimus tendon is sewn to the underside of the anterior tendinous attachment of the gluteus medius to the greater trochanter fragment. The greater trochanter fragment is reduced and the wire cables tied over the bone with or without a cable grip depending on the quality of the bone. If the greater trochanter fragment cannot be reduced completely, part of the proximal bone is shelled out to prevent impingement. If the greater trochanter fragment has no bony apposition, the entire bone is removed, leaving the gluteus medius still attached to the vastus lateralis fascia by the intermuscular septum distally. Two 3mm cottony dacron sutures are placed horizontally around the proximal femur in a similar pattern as described with the wire cables.

In cases with well-fixed cemented or cementless femoral components that require removal for malposition, or to facilitate cement removal in cases with loose cemented stems but well-fixed cement mantles, an extended greater trochanteric osteotomy approach is very useful. This approach is very similar to the greater trochanter slide approach, except part of the lateral femoral diaphysis is taken with the greater trochanter. The diaphyseal segment can be as long as needed to assist with cement or component removal. It is preferred to first remove a cemented femoral component through a posterior arthrotomy after releasing the external rotators. The vastus lateralis fascia is incised longitudinally one centimeter anterior to the intermuscular septum.

The posterior vastus lateralis is elevated from the intermuscular septum and femoral diaphysis just anterior to the intermuscular septum, leaving the majority of the vastus lateralis muscle still attached to the lateral cortex. A 3.2mm drill bit is drilled through the posterior cortex, cement mantle, and anterior cortex to mark the distal end of the osteotomy in order to remove the lateral one-third of the diameter of the diaphyseal cortex. The position of the distal end of the osteotomy is determined from preoperative planning or by using the removed femoral component as a gauge. Another drill bit is inserted proximally through the posterior greater trochanter exiting the anterior greater trochanter just medial to the anterior insertion of the gluteus medius. An oscillating saw is then used to make a longitudinal osteotomy through the posterior greater trochanter and posterior femoral diaphysis, through the cement mantle, then blindly through the anterior cortex using the drill bits still in the bone for the angle of the bone cut. The drill bits are removed, the osteotomy completed, then opened like a book, hinged on the anterior periosteum and vastus musculature. This gives excellent exposure to remove the cement.

If the cemented femoral component cannot be removed first or if one has a well-fixed cementless femoral component, the technique is modified because the femoral component will prohibit making the anterior osteotomy through the femoral canal. The vastus lateralis is elevated from the femoral shaft to allow direct visualization of the anterior lateral cortex for the anterior part of the longitudinal osteotomy. Curved wide Lambotte osteotomes are inserted from posterior to anterior to carefully pry open the osteotomy. Alternately, the anterior lateral cortex is multiply perforated with a pencil tipped burr or drill bit, and the anterior portion of the osteotomy cracked open with Lambotte osteotomes.

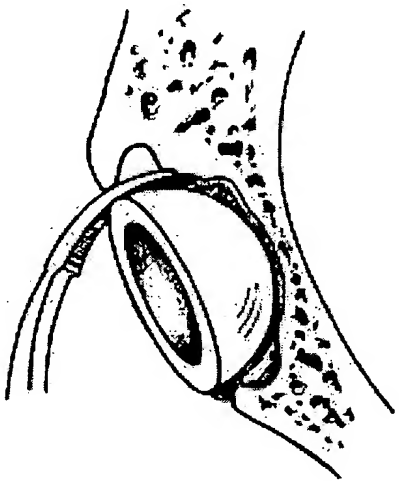
The extended greater trochanter osteotomy-muscle sleeve can be retracted anteriorly, and the femur retracted posteriorly to allow exposure of the acetabulum. The femur can then be prepared either with or without the osteotomized fragment temporarily secured in place. The cementless femoral component is then inserted and the osteotomy reduced. An acorn-shaped burr is used on the osteotomy fragment to get it perfectly fit. If the new femoral component is to be cemented in place, a trial reduction with the femoral trials in place must be performed first. The osteotomy is reduced to determine its eventual position and secured with wire cables. The trial femoral component is removed and the final component cemented in place.

Acetabular Preparation for Revisions

Removal of Primary Component
Soft tissue must be excised circumferentially to expose the implant-cement-bone interfaces. A standard curved 1/4 - to 3/8-inch osteotome is used circumferentially to separate the implant-cement or bone-cement interface. Be careful in areas of thin bone such as the midposterior and anterior wall, since the wedging effect of the osteotome may cause a fracture.

Next, a long, curved acetabular cement osteotome is placed superiorly around the cup and in the area of previous cement plugs to divide them (Figure 39).

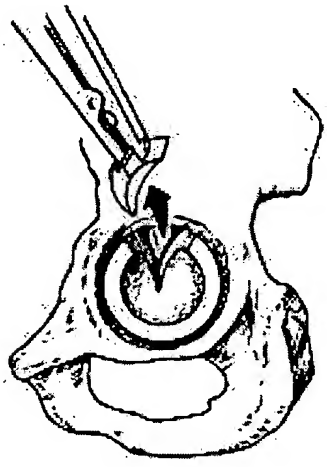
Figure 39



Occasionally, the acetabular component will be so loose as to allow easy extraction with a Kocher clamp or large rongeur. This is done by torquing the socket out, rather than by using a strong tensile pull to remove it.

If the acetabular component is a cemented all-polyethylene cup and more firmly fixed, the polyethylene can be divided first with a high-speed burr or osteotome. A pie-shaped portion may then be removed, allowing the cup to collapse and be extracted (Figure 40).

Figure 40



If the cup is cemented and metal-backed, extraction may be more difficult, as the technique of dividing the polyethylene will not be helpful. The insert extraction tool can be threaded into the center of the polyethylene if the polyethylene insert is thick. Gentle axial blows are applied to the rod. Usually thin curved osteotomes will have to be used until all the cement-bone attachments are divided, freeing the cup. In extreme cases, the cup may need to be cut with metal-cutting burrs or high-speed tools.

If the cup is noncemented, the polyethylene liner is removed first. A 4.5mm hole is made in the polyethylene liner and the insert extractor inserted until the liner pops out (see Figure 30, page 16). Any screws through the shell are now removed. Thin curved osteotomes are placed around the shell releasing as much of the bone-prosthesis interface as possible without fracturing the acetabular walls. If a threaded dome hole is present, the original cup insertion tool or any purposely designed extraction tool is attached. If the dome hole is not threaded, special spanner tools which attach to the outer rim locking ring are used. The remaining bony attachments are sheared through using rotational or torsional movements on the shell. Direct axial blows are avoided due to the risk of pulling off large pieces of bone still attached to the shell. Alternatively, torsional blows to the shell rim are used to rotate the shell and shear off the remaining bony attachments.

Preparation of Bony Bed

Once the shell has been extracted, the remaining cement and cement plugs are removed by dividing them into smaller pieces. The fibrous membrane is then removed with a large double-handed curette.

If the remaining bone is very sclerotic or impregnated with soft tissue, a high-speed burr may be used to improve the bony surface. If sclerotic non-bleeding bone remains after conservative burring, excessive bone should not be burred away; rather, the sclerotic area should be perforated with multiple small drill holes.

The bony anatomy is surveyed to determine the presence of any major bony defects which may necessitate bulk bone grafting or the use of reinforcement roof rings or cages.

Ideally, an attempt should be made to reestablish the center of the new acetabular component within 1cm to 1.5cm of the anatomic center. The inferior medial cotyloid notch is the best reference point to determine this intraoperatively. The site of the transverse ligament should be located and the medial/inferior edge of the reamer kept at this level with initial reaming.

Another goal is to fill the bony defect maximally with the shell. A full rim fit of the shell is the optimal result. In the typical situation of a small superolateral bone deficiency, this can usually be achieved by reaming to a larger size (Figure 41). However, the extent of reaming will be limited by the remaining anterior and posterior walls; the surgeon should not over ream to the point of excessive removal of these walls (Figure 42*). Reaming is performed at 40 degrees abduction and 20 degrees anteversion.

Figure 41

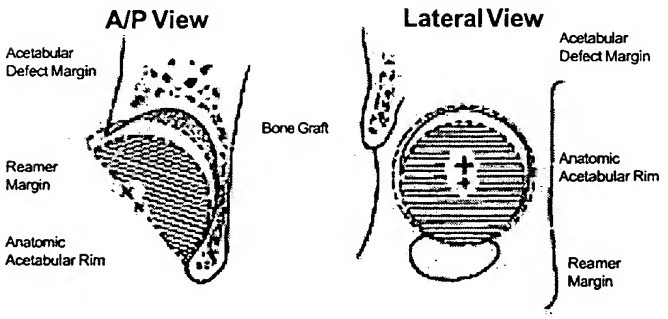
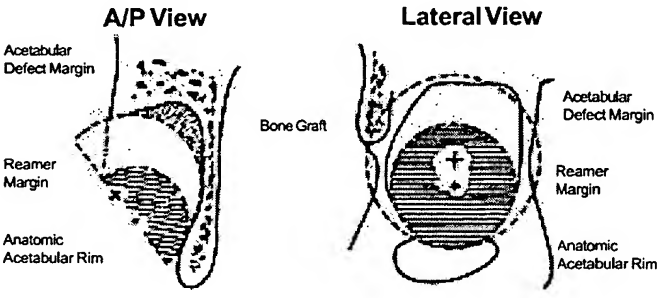


Figure 42



*IMPROPER TECHNIQUE

If a rim fit can be achieved by reaming more proximally, yet keeping the inferior edge of the reamer within 1cm to 1.5cm of the inferior acetabular notch, this is a reasonable alternative (Figure 43).

If there is a superolateral acetabular defect greater than 1.5cm, acetabular reconstruction will require either the use of a bulk bone graft, ring support, or very proximal cup placement. More proximal cup placement (high hip center) may result in less bone containment because the pelvis gets narrower and shallower as one moves proximal to the anatomic acetabular position. Proximal cup positioning results in a higher risk of dislocation from impingement. When the cup is placed very proximal, the hip musculature will need to be placed under adequate tension. This requires use of long modular heads, placing the femoral component proud, or using a calcar replacement femoral stem. The use of a protrusio metal shell and/or a protrusio polyethylene insert with the acetabular reconstruction will lower the center of head position. The use of a very long modular head on the neck may increase lateral offset so much that it prevents adequate anterior or posterior soft tissue repair thereby increasing the risk for dislocation. However, if the patient is elderly or with significant medical risks, proximal cup placement is a reasonable choice.

If the superolateral defect is greater than 1cm to 1.5cm, a bulk supporting allograft may be considered and the acetabular component placed in an anatomic position (Figure 44).

Figure 43

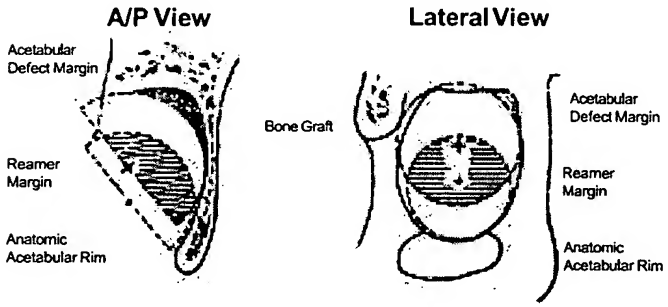
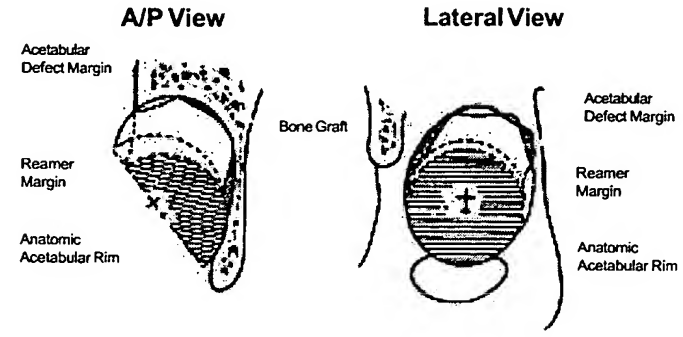


Figure 44



The acetabulum is reamed with the largest reamer that fits within the anterior and posterior walls, maintaining the reamer equator below a line connecting the anterior inferior spine anteriorly and the ischium posteriorly (Figure 45). This will capture the shell and prevent superior migration.

If the superolateral defect is greater than 25 percent to 30 percent of the cup coverage, additional support for the cup is needed. Most critical is that the superior cup is buttressed against iliac bone at least medially or the cup will migrate into the graft.

An allograft femoral head, proximal femur, or distal femur of the appropriate size should be obtained and cleared of cartilage and soft tissue. The graft is reamed with a concave reamer (cup arthroplasty reamer) to make it spherical, and the superolateral defect is reamed with the standard convex acetabular reamer that corresponds to the diameter of the graft or 1mm smaller. This provides a stable bed for the graft (Figure 46).

With reverse reaming, cancellous bone slurry is packed into any remaining bony defects. The allograft is impacted into the defect and held with two or three large Steinmann pins. The allograft is progressively reamed in the anatomic acetabular position until the previously reamed host bone is maximally contacted. Anterior-posterior wall contact by the cup is necessary as is contact with medial iliac bone. If this area of contact is not available then consideration for ring support must be given.

Additional bony defects are filled with cancellous bone and packed with reverse reaming.

Figure 45

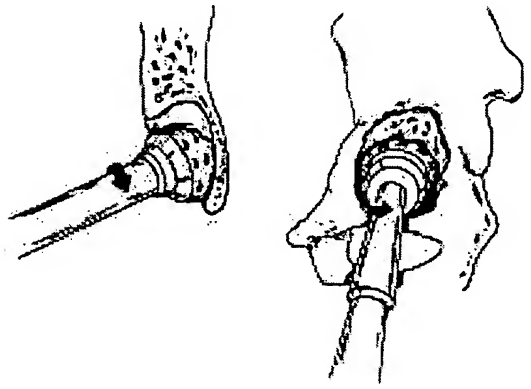
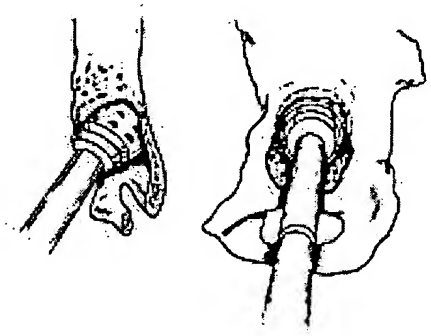


Figure 46



With medial defects, the dome of the cup can protrude into the defect as long as the protruded portion does not exceed 25 to 30 percent of the surface of the cup. Technically this is accomplished by reaming the acetabulum large enough to achieve rim support without seriously weakening the anterior or posterior walls (Figure 47). The remaining medial defect can be packed with cancellous bone chips. If support is suspect or the cup contact with host bone is less than 50 percent, it is preferred to ream the acetabulum to the base and use a protrusio shell and/or a protrusio liner to bring the center of rotation to the anatomic center. Any remaining small bony defects should be filled with cancellous bone chips and packed with reverse reaming. Alternatively, a bulk allograft can be inserted superomedially with the same technique as outlined for the superolateral bulk graft.

If a posterior wall defect is present that results in more than 25 to 30 percent of exposed cup, a bulk allograft may be needed to assist with cup support. The intertrochanteric portion of a proximal femoral or a distal femoral allograft is ideal for this application, since the diameter of each is usually greater than that available with femoral heads.

The bulk allograft is temporarily secured with Steinmann pins during reaming. After the acetabular shell is inserted, a posterior buttress plate is applied (Figure 48). Spanning the graft will enable the plate and screws to resist extreme forces that may be placed on the posterosuperior acetabulum when the patient rises from a chair or climbs stairs.

Figure 47

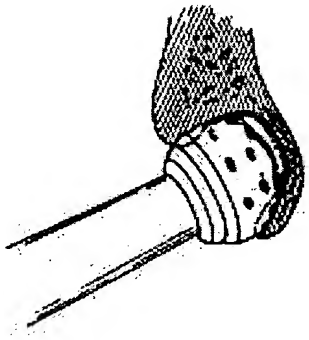
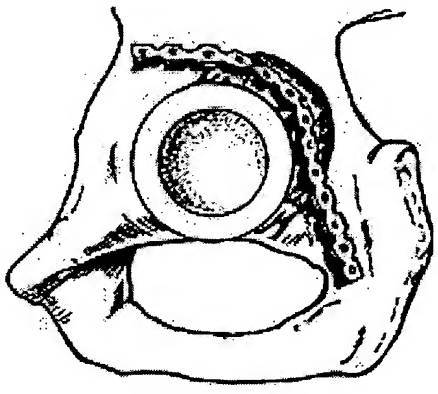


Figure 48



Trialing of Multi-Hole Shell
Initially, the same size shell trial as the final reamer is inserted. The shell aligner/positioner, keying off the dome tear drop, is threaded into place (see Figure 13, page 8). The shell trial is impacted into the acetabulum at a 40 degree abduction angle and a 20 degree anteversion angle. Seating is verified through the trial holes. If a tight fit is not present, the trial that is one size (2mm) larger than the final reamer is usually needed to obtain a tight pressfit. Ream the rim of the acetabulum an additional 1-2mm first. It is rare that a shell 3mm larger than the final reamer will be necessary. Routine 2-3mm press fits should be avoided in sclerotic bone, since fracture may occur. The trial inserts can be used with the trial shell or with the actual implant (See Figures 14 & 15, page 9).

Trialing of the Protrusio Shell
If the shell trial sits more than one centimeter proximal or inside the normal acetabular rim, the protrusio shell should be used. The protrusio shell trial is inserted with the shell aligner/positioner at 40 degrees of abduction and 20 degrees of anteversion (see Figure 13, page 8 and Figures 16 and 17, page 10). Seating is verified through the shell trial holes. Standard, hooded and protrusio trial liners can be used with the shell trial or with the actual implant (see Figures 14 & 15, page 9).

Note: The protrusio porous shell provides an additional 10mm metal buildup at the dome of the implant for lateralization of the center of rotation.

Implantation of the Multi-Hole or Protrusio shells
The acetabular multi-hole or protrusio shell is positioned into the acetabulum using the same acetabular shell aligner/ positioner as used with the shell trials. The shell holder references a 40 degree abduction angle and a 20 degree anteversion angle when the vertical rod is 90 degrees to the body and horizontal rod points to the shoulder (see Figures 16 & 17, page 10). The implant is impacted into position and the aligner/positioner removed.

Optional Screw Placement
If screw fixation is desired, the drill is used first in the middle hole of the lower iliac (superior) row of the shell (See Figure 22, pg. 13). The drill bit is inserted until the inner cortex is drilled or the full length of the 50mm drill bit is achieved.

A depth gauge is inserted to determine the appropriate bone screw length (See Figure 23, pg. 13). The tap is used if the host bone adjacent to the shell is very sclerotic or if hard bulk allograft bone is present (See Figure 24, pg.14).

Sulzer Orthopedics 6.5mm cancellous bone screws should be used to secure the shell. The first screw is inserted with a U-joint hex head screwdriver until fully seated (See Figure 25, pg.14). One to two additional holes are drilled in the ilium as needed to supplement fixation and screws inserted. Added stability is achieved if the screw grabs the inner cortex. However, care should be taken when drilling the posterior iliac screw hole not to plunge into and risk damaging the sciatic nerve or superior gluteal artery.

If possible, one screw should also be placed in the ischium or pubis to resist tensile stresses on the shell. If a superior or superolateral bulk allograft is used, the screws will help fix the graft as well as the shell, by extending through the graft into host bone.

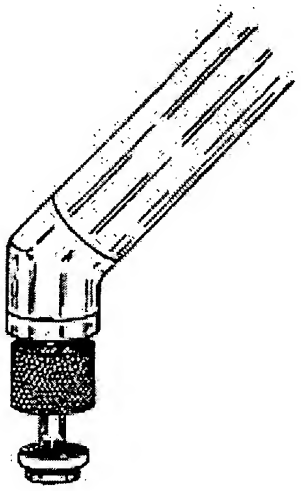
WARNING: Sulzer Orthopedics bone screws are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

*For selection of the appropriate cup size, see example on page 9.

Optional Screw Hole Seals
Any remaining open screw holes can then be plugged with the screw hole seals (available in a separate four-pack). To do this, the fixed angle driver is assembled to the revision T-handle and 3.5x16.5mm hex bit (Figure 49). Then, the screw hole seal is pressed firmly onto the end of the hex bit to secure it (Figure 50). This should capture the screw hole seal onto the hex bit and prevent droppage.

Figure 49

Figure 50



The screw hole seals are slightly out of round and tighten as a cam, developing an interference fit with the round screw hole. The screw hole seal is placed into the chosen open screw hole of the shell and rotated until it drops in (Figure 51). It is then rotated until tight by turning the T-handle approximately 45 degrees clockwise. This engages the cam-lock feature and minimizes debris passage (Figure 52). Make certain the screw hole seals are flush or below the surface of the implant to avoid interference with insert seating. If needed, the screw hole seals can be removed and reinstalled by turning them counterclockwise to the original starting position. This is recommended if uneven or proud seating of the screw hole seals occurs.

Figure 51

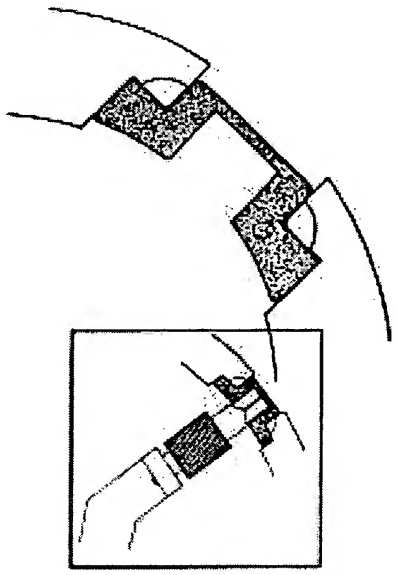
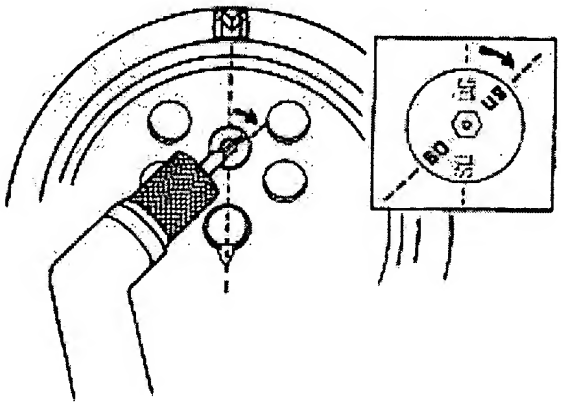


Figure 52



Note: The screw hole seals are engraved with the letters "SOUS" such that alignment of these letters with the longitudinal axis of the shell (from rim to dome) will allow optimal seating prior to rotation (Figure 53).

WARNING: Do not assemble screw hole seals prior to impacting the shell into the patient. Only in vivo installation of the screw hole seals is recommended.

The fixed angle driver is then removed and any other open screw holes plugged in the same manner.

The trial acetabular insert of the size corresponding to the shell is selected. A hooded insert is preferred in most revision cases. The optimal position of the hood can be determined by using the hooded trial inserts. The trial inserts can be secured by threading the captured screw into the dome hole with the straight hex head screwdriver (See Figure 15, page 9).

Note: All shells are provided with a titanium dome plug. Be sure to install the dome plug to all shells with the straight hex head screwdriver prior to impaction of insert. Once the dome plug is installed, trial inserts cannot be used without removing the dome plug (Figure 54).

Figure 53

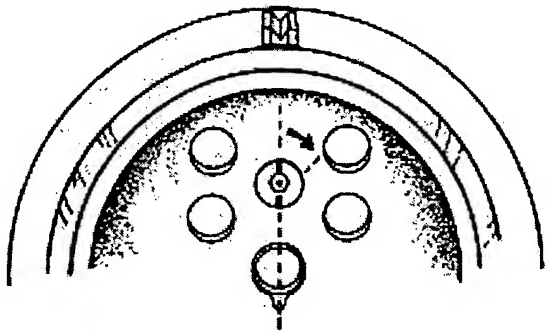
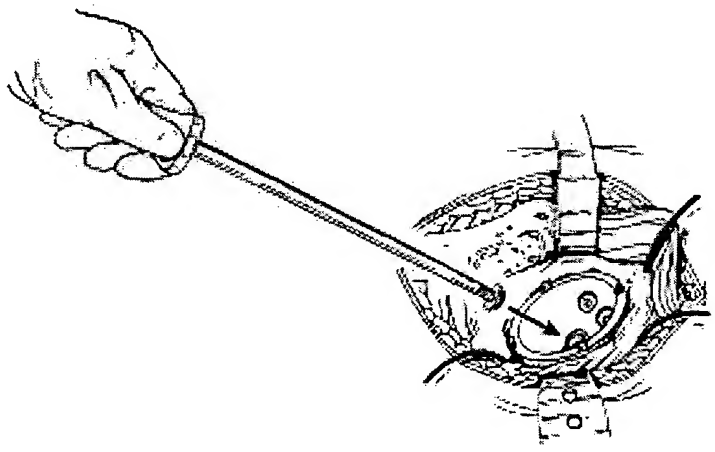


Figure 54



Closure

Posterior lateral approach
A No. 2 or No. 5 Ethibond horizontal suture is passed through the piriformis tendon and posterior capsule. A second suture is placed 1.5cm distal to the first, passing through the short external rotators and posterior capsule. Two or three small holes are drilled into the posterior edge of the greater trochanter opposite the sutures, which are passed through the drill holes with a Hewson suture retriever or similar device. The gluteus maximus insertion is closed with a No. 1 absorbable suture. By pulling on the Ethibond sutures, the posterior capsule and rotators are then drawn snugly against the greater trochanter with the leg extended and externally rotated (Figure 55). The suture strands are then tied together. This will pull the capsule and rotators back into an anatomic position. After closing the quadratus and bringing the trochanteric bursa over the external rotators with a 2-0 absorbable suture, the dead space is eliminated. A wound suction device is placed in the wound at this point. A drain is not needed if the surgery is completed within 1.5 hours.

The fascia of the gluteus maximus, iliotibial band and subcutaneous tissue are closed in layers. Staples or a subcuticular closure with steri strips are applied. If the patient has a thick subcutaneous layer, a second wound suction device may be placed into the subcutaneous tissue. An abduction pillow or "sling and springs" is placed on the patient prior to transfer to the recovery room.

Anterior lateral approach
The anterior gluteus medius/gluteus minimus/anterior vastus lateralis flap with its sliver of bone is reduced to its bony bed on the anterior greater trochanter. Three No. 5 Ethibond or Mersilene sutures are used around the sliver of bone and through cortical bone on either side of the bony bed on the trochanter. A permanent suture is placed through the gluteus minimus tendon and the tendinous portion of the posterior gluteus medius. Additional sutures are placed in the gluteus medius fascia and vastus lateralis fascia (Figure 56). The hip is extended and externally rotated to check the quality of the repair. One suction drain is inserted into the joint under the anteroinferior edge of the gluteus medius.

The fascia lata and gluteus maximus fascia, subcutaneous tissue and skin are closed in layers. An additional drain is placed into the subcutaneous tissue if needed. The skin is closed with a running subcuticular suture reinforced with steri-strips.

Figure 55

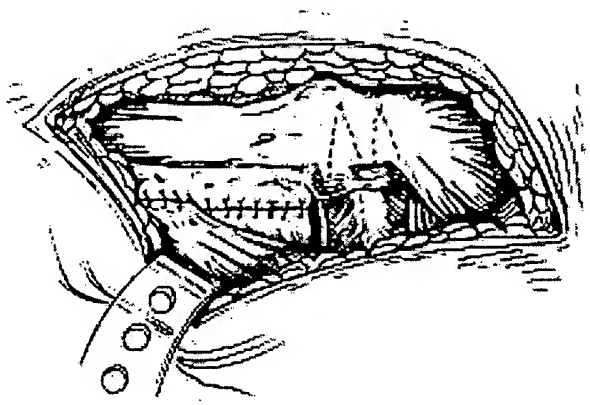
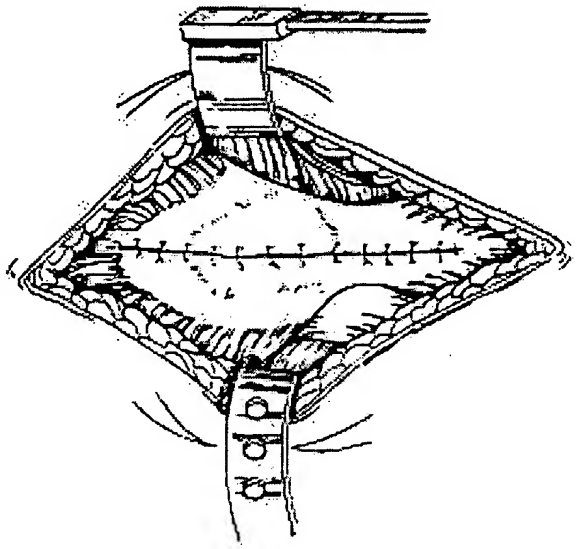


Figure 56



Sulzer Orthopedics

Converge Porous Acetabular System

SULZER *MEDICA*
Sulzer Orthopedics

270064
CE 0123

Important Information for the Operating Surgeon

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

Description of Prosthesis

The Converge™ Acetabular System consists of a porous coated metallic shell that utilizes a polyethylene snap-in liner. Converge Acetabular components are intended for resurfacing of the acetabulum during total hip arthroplasty and are available in a variety of sizes and designs to address different clinical situations. The shells are manufactured from Ti-6Al-4V alloy (ASTM F136) and are coated with Cancellous-Structured Titanium™ (CSTi™) Coating made from commercially pure titanium (ASTM F1580). The system includes several shell designs for both primary and revision applications, including the following:

(1) Rim Flare - a hemispherical shell with an offset outer radius and spikes in the rim region, which permits loads to be transmitted to the periphery of the outer surface

(2) Cluster Hole - a hemispherical shell with a closely grouped series of plugged screw holes manufactured from Ti-6Al-4V (ASTM F136) which may be removed intraoperatively for additional screw fixation, if desired

(3) Multi-Hole - a hemispherical shell with multiple screw holes around the periphery

(4) Protrusio - a shell that has 10 mm of additional material thickness in the medial wall over that of a standard hemispherical cup, to address protrusio deficiencies in the acetabulum.

Those screwholes that are not utilized for fixation on the Multi-hole and Protrusio Shells may be closed with plugs that are manufactured from commercially pure titanium (ASTM F67) or titanium alloy (Ti-6Al-4V, ASTM F136). A dome hole plug made of commercially pure titanium (ASTM F67) is provided for use with shell components of this system. All the shell designs share common internal geometry and locking mechanism thereby accepting any of the acetabular liners designed for this system. The acetabular liners are offered in various configurations in order to address different clinical situations and are available in a variety of sizes to accommodate available femoral head components. The acetabular liners are manufactured from either of two types of Ultra-High Molecular Weight Polyethylene (UHMWPe), both conforming to ASTM F648. One type is gamma irradiated in an oxygenless environment and carries no special designation. The other is irradiated by electron beam under melting conditions and carries the trade name DURASUL™. Converge Acetabular Components are recommended for use with all Sulzer Orthopedics total hip replacement devices.

Information for Use

The advancement of total joint replacement has provided the surgeon a means of restoring mobility and reducing pain for many patients. While total hip replacements are largely successful in attaining these goals, no total joint replacement can be expected to withstand the activity levels and loads of normal healthy bone.

In using the Converge™ Acetabular Components, the surgeon should be aware that the following factors can be of extreme importance to the eventual success of the procedure:

A. Correct and initial size selection of the implant is extremely important. The potential for success in total joint replacement is increased by selecting the proper size, shape and design of the implant. This total joint prosthesis requires careful seating and adequate bone and cement support, and should be restricted to limited functional stress.

B. In selecting patients for total joint replacement, the following factors can be of extreme importance to the eventual success of the procedure:

1. The patient's weight: An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the cement and/or device (if the device is cemented).
2. The patient's occupation or activity: If the patient is involved in an occupation or activity, that involves substantial walking, running, lifting and/or muscle strain, the resultant forces can cause failure of the cement and/or device (if the device is cemented).
3. A condition of senility, mental illness, or substance abuse, eg., alcoholism: These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant failure or other complications.
4. Certain degenerative diseases: In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected life of the device. In such cases, total hip replacement can only be considered as a temporary relief from pain or as an intermediate procedure.
5. Foreign body sensitivity: Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
6. Infection: Local infection, recent or chronic, may be a contraindication for the use of a total joint replacement. Extreme care should be used in patient selection in the event of recent or chronic infection.

C. Careful handling of all components is very important.

1. Inspect packages for punctures and other damage prior to surgery.
2. The Converge™ Acetabular porous coated devices, particularly surfaces to be mated with polyethylene components, should be protected from mechanical damage and not be allowed to contact any metallic or other hard surface.
3. Use caution in handling porous-coated components to prevent contamination of the coating and entrapment of cloth or other debris. The CSTi coating should not be allowed to contact cloth or other lint-shedding or dirty materials prior to implantation. Conventional cleaning techniques cannot be relied upon to remove lint, dirt, or body tissue from CSTi.

Assembly of Components

The Sulzer Orthopedics Converge™ Acetabular Component is placed into position in two steps. First, the desired metal shell is placed into a reamed acetabulum. Then the liner is positioned to align the slots of the insert with the anti-rotation tabs of the shell. Utilizing the insert impactor, the liner is malleted into place, snapping it into the locking groove of the shell.

Indications and Contraindications

Indications and contraindications for the use of the Converge™ Acetabular Components may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as nonoperative treatment, arthrodesis, and others.

Patient selection will be largely dependent on patient's age, general health conditions of available bone stock, prior surgery and anticipated further surgeries. Prosthetic replacement is generally only indicated for patients who have reached skeletal maturity.

A. Indications

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
3. Revision of previously failed hip arthroplasty.

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Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient (see "Warnings and Precautions"), and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

B. Contraindications

1. Patient's physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriate sized implant: e.g., previous surgery, insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy), or other conditions that lead to inadequate skeletal fixation.
2. Active infection of the hip joint, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.
3. Other conditions that will place excessive demands on the joint:
- Charcot's joints
- muscle deficiencies
- multiple joint disabilities
- refusal to modify postoperative physical activities
- obesity.

4. Conditions that tend to impose severe loading on the affected extremity include, but are not limited to, the following:
- obesity
- heavy labor
- active sports
- history of falls
- general neurological abnormalities or neurological conditions (e.g., mental illness, senility, drug use, alcoholism) which tend to preempt the patient's ability or willingness to follow the surgeon's postoperative instructions.

5. Physical conditions that tend to adversely affect the stable fixation of the implants include, but are not limited to, the following:
- marked osteoporosis
- systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies)
- history of general or local infectious disease
- tumors and/or cysts of the supporting bone structure
- suspected allergic reactions to metals, polyethylene, bone cement
- other joint disability (i.e., knees or ankles)
- severe deformity leading to impaired anchorage or improper positioning of implants.

Warnings and Precautions

A. Preoperative

1. The preoperative planning and surgical technique for implantation of the Converge™ Acetabular Components represent principles that are basic to sound surgical management in total hip replacement. Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is suggested in the performance of this surgery. Review of the use and handling of these instruments is important. Bent or damaged instruments may lead to improper implant position and result in implant failure. A surgical technique brochure fully describing the procedure is available from Sulzer Orthopedics Inc.
2. When total hip replacement is being considered, particularly for the young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following the doctor's preoperative instructions.
3. Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively.
4. X-ray templates should be used to estimate implant sizes, placement and joint alignment. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra implant components are recommended. All packages and implants should be thoroughly inspected prior to surgery for possible damage (see "Sterilization" section).
5. The correct handling of the implant is extremely important. The Converge™ Acetabular Components should be used without nicks, scratches, or other alterations; these can produce defects and stresses that may become the focal point for eventual failure of the implant. Polyethylene liners, once snapped into place, should not be removed and reinserted.
6. A surgical implant must not be reused under any circumstances. Once implanted and subsequently removed, an implant should be discarded. Even though the implant appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Only new implants may be used. Do not alter implant prior to use.
7. The use of polymethylmethacrylate (PMMA) bone cement can be helpful in securing, supporting and stabilizing certain devices in bone, but it neither replaces the support function of sound bone nor eliminates the need for additional support during healing. In using cement for implant fixation, care should be used to ensure complete cement support on all parts of the device embedded in the bone cement to help prevent possible stress concentrations that may lead to failure.
8. Sulzer Orthopedics Inc. provides bone screws for use with this device in the event that added fixation is desired by the operating surgeon. These bone screws are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
9. The safety and effectiveness of the use of this device in bilateral applications have not been established.

B. Intraoperative

1. The correct selection of the implant is extremely important. Selection of the implant refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.
2. Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the metal/plastic/articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.
3. Stem and cup positioning and neck length are of critical importance. Subluxation, dislocation, and/or fracture of components may result due to muscle looseness and/or malpositioning of components.

C. Postoperative Care

Postoperative care is important. The patient should be instructed on the limitations of this device and should be cautioned regarding the load-bearing, range of motion, and activity levels permissible. Early load-bearing should be carefully controlled.
1. Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation or thromboembolism.

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270063 continued

2. Postoperative therapies, patient handling (e.g., changing dressings, placing on bedpans, etc.) and patient activities should be structured to prevent excessive loading of the operative hip. The surgical procedure chosen (e.g., trochanteric osteotomy), the patient's age and/or bone quality may necessitate extending the period of limited weight bearing.
3. Periodic x-rays are recommended for close comparison with postoperative x-rays to detect long-term evidence or progressive changes in implant position or loosening. X-rays may also detect evidence of bending, cracking and/or disassembly of components or cracking of the cement.
4. The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

D. Adverse Events
The potential adverse effects of the Converge™ Acetabular Components are similar to those occurring with any total hip replacement. These effects are often attributable to factors listed under "Warnings and Precautions" and commonly include:
1. Changing position of the prosthesis (bending, fracture and/or disassembly of components) with or without clinical symptoms.
2. Perforation, fissure, fracture of the acetabulum, femur or trochanter and/or trochanteric avulsion.
3. Subluxation, dislocation, decreased range of motion, and shortening or lengthening of the extremity.
4. Fractures of the femur. Postoperative fractures are usually stress fractures. Fractures are usually evidence of defects in the cortex due to prior screw holes and misdirected reaming and/or inadequate maldistributed bone cement. Intraoperative fractures are usually associated with revision surgery deformity and/or severe osteoporosis.
5. Ectopic ossification.
6. Early or late infection.
7. Cardiovascular disorders including damage to blood vessels (iliac, obturator and femoral artery), wound hematoma, venous thrombosis, pulmonary embolism and myocardial infarction.
8. Temporary or permanent neuropathies, including femoral, sciatic, peroneal or obturator.
9. Pulmonary disorders including pneumonia and atelectasis.
10. Aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, femoral medialization, or muscular deficiencies.
11. Excessive wear of the acetabular component from damage to mating wear surfaces or debris particles.
12. Tissue reactions and allergy to corrosion or wear products.
13. Urological complications, especially urinary retention and infection.
14. Aseptic loosening.
15. Possible detachment of coating (CSTi) could be associated with increased metal or third body debris.
16. Other complications associated with general surgery, drugs, or ancillary devices used, blood, etc.

Sterilization
Unless otherwise indicated, all components are provided sterile and are supplied packaged in protective trays.
Shells are sterilized by a minimum of 25 kGy (2.5 Mrads) of gamma irradiation. Standard polyethylene components are packaged with an oxygen absorber and are also sterilized by a minimum of 25 KGy (2.5 Mrad) of gamma irradiation. Durasul acetabular inserts are sterilized using ethylene oxide gas.
Sulzer Orthopedics INC. DOES NOT RECOMMEND RESTERILIZATION OF IMPLANTABLE DEVICES.
Additional information regarding the Converge™ Acetabular system may be obtained from Sulzer Orthopedics Inc.
THE CONVERGE™ ACETABULAR SYSTEM IS INTENDED FOR USE WITH OR WITHOUT BONE CEMENT.

INTER-OP™ METASUL® ACETABULAR INSERT 270054

WARNING: THE INTER-OP METASUL ACETABULAR INSERT IS TO BE USED ONLY WITH THE METASUL FEMORAL HEAD and Sulzer Orthopedics shells designed to accept this insert.

Description of Prosthesis
The Inter-Op Metasul Acetabular Insert is an ultra-high molecular weight polyethylene (UHMWPE, ASTM F648) acetabular shell liner with an inner diameter that contains a metal inlay. The metal inlay is manufactured from PROTASUL®-21WF, a forged CoCr alloy (ISO 5832-12). Two PROTASUL®-10(CoCr alloy) pins are press-fit in the metal inlay. The outside diameter of the polyethylene backing is designed to integrate with the shell component. The Inter-Op Metasul Acetabular Insert is available with a 28mm inner diameter and outside diameters ranging from 49-81mm (2mm increments).

Information for Use
The advancement of total joint replacement has provided the surgeon a means of restoring mobility and reducing pain for many patients. While total hip replacements are largely successful in attaining these goals, no total joint replacement can be expected to withstand the activity levels and loads of normal healthy bone. In using the Inter-Op Metasul Acetabular Insert, the surgeon should be aware that the following factors can be of extreme importance to the eventual success of the procedure:

A. Correct initial size selection of the implant is extremely important. The potential for success in total joint replacement is increased by selecting the proper size, shape and design of the implant. Total joint prostheses require careful seating and adequate bone and cement support (if cement is used), and should be restricted to limited functional stress.
B. In selecting patients for total joint replacement, the following factors can be of extreme importance to the eventual success of the procedure:
1. The patient's weight: An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the device and/or cement (if the device is cemented).
2. The patient's occupation or activity: If the patient is involved in an occupation or activity that involves walking, running, lifting and/or muscle strain, the resultant forces can cause failure of the device and/or cement (if the device is cemented).
3. A condition of senility, mental illness, or substance abuse, e.g., alcoholism: These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant failure or other complications.
4. Certain degenerative diseases: In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected life of the device. In such cases, total hip replacement can only be considered as a temporary relief from pain or as an intermediate procedure.
5. Foreign body sensitivity: Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
6. Infection: Local infection, recent or chronic, may be a contraindication for the use of a total joint replacement. Extreme care should be used in patient selection in the event of recent or chronic infection.
C. The Inter-Op Metasul Acetabular Insert should be protected from mechanical damage and not be allowed to contact any metallic or other hard surface.

Assembly of Components
NOTE: ONLY SULZER ORTHOPEDICS INSTRUMENTATION DESIGNED FOR PLACEMENT OF THE METASUL COMPONENTS SHOULD BE USED. USE OF OTHER INSTRUMENTATION MAY RESULT IN DAMAGE TO THE COMPONENTS, COMPLICATIONS AND/OR DEVICE FAILURE.

The acetabular component is placed into position in two steps. First, one of the metal acetabular shells is placed into a reamed acetabulum. Then the Inter-Op Metasul acetabular insert with the integral metal inlay is positioned to align the anti-rotation pins with the mating slots and the central insert peg with the hole in the top of the shell. Utilizing the Inter-Op Metasul Insert Impactor, the liner is malleted into place, snapping it into the locking groove of the shell.

Indications and Contraindications
Indications and contraindications for the use of the Inter-Op Metasul Acetabular Insert may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as nonoperative treatment, arthrodesis, and others. Patient selection will be largely dependent on patient's age, general health, conditions of available bone stock, prior surgery and anticipated further surgeries. Prosthetic replacement is generally only indicated for patients who have reached skeletal maturity.

A. Indications:
1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, posttraumatic arthritis, or avascular necrosis and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
3. Revision of previously failed hip arthroplasty.

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient (see "Warnings and Precautions"), and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

B. Contraindications
1. Patient's physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant: e.g., previous surgery, insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy) or other conditions that may lead to inadequate skeletal fixation.
2. Active infection of the hip joint, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.
3. Other conditions that will place excessive demands on the joint:
- Charcot's joints
- muscle deficiencies
- multiple joint disabilities
- refusal to modify postoperative physical activities
- obesity.
4. Conditions that tend to impose severe loading on the affected extremity include, but are not limited to, the following:
- obesity
- heavy labor
- active sports
- history of falls
- general neurological abnormalities or neurological conditions (e.g., mental illness, senility, drug use, alcoholism) which tend to preempt the patient's ability or willingness to follow the surgeon's postoperative instructions.
5. Physical conditions that tend to adversely affect the stable fixation of the implants include, but are not limited to, the following:
- marked osteoporosis
- systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies)
- history of general or local infectious disease
- tumors and/or cysts of the supporting bone structure
- suspected allergic reactions to metals, polyethylene, bone cement
- other joint disability (i.e., knees or ankles)
- severe deformity leading to impaired anchorage or improper positioning of implants.

Warnings and Precautions
A. Preoperative
1. The preoperative planning and surgical technique for implantation of the Inter-Op Metasul Acetabular Insert represents principles that are basic to sound surgical management in total hip replacement. Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is required in the performance of this surgery. Review of the use and handling of these instruments is important. Bent or damaged instruments may lead to improper implant position and result in implant failure. The surgical technique brochure fully describing this procedure is available from Sulzer Orthopedics Inc.
2. When total hip replacement is being considered, particularly for the young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following the doctor's preoperative instructions.
3. Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively. Information more fully describing the material composition of the Metasul component is available from Sulzer Orthopedics Inc.
4. X-ray templates should be used to estimate implant sizes, placement and joint alignment. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra implant components are recommended. All packages and implants should be thoroughly inspected prior to surgery for possible damage (see "Sterilization" section).

5. The correct handling of the implant is extremely important. The Inter-Op Metasul Acetabular Insert should be used without nicks, scratches, or other alterations; these can produce defects and stresses that may become the focal point for eventual failure of the implant. This device, once snapped into place, should not be removed and reinserted.

6. A surgical implant must not be reused under any circumstances. Once implanted and subsequently removed, an implant should be discarded. Even though the implant appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Only new implants may be used. Do not alter implant prior to use.

7. The use of polymethylmethacrylate (PMMA) bone cement can be helpful in securing, supporting and stabilizing certain devices in bone, but it neither replaces the support function of sound bone nor eliminates the need for additional support during healing. In using cement for implant fixation, care should be used to ensure complete cement support on all parts of the device embedded in the bone cement to help prevent possible stress concentrations that may lead to failure.

8. The safety and effectiveness of the use of this device in bilateral applications have not been established.

B. Intraoperative

1. The correct selection of the implant is extremely important. Selection of the implant refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.

2. Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the head/liner articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.

3. Stem and cup positioning and neck length are of critical importance. Subluxation, dislocation, and/or fracture of components may result due to muscle looseness and/or malpositioning of components.

4. WARNING: The Inter-Op Metasul Acetabular Insert is to be used only with the Metasul femoral head and Sulzer Orthopedics shells designed to accept this insert. Only Sulzer Orthopedics instruments should be used for placement of Metasul components.

High precision manufacturing allows for optimal articulating surface geometry. Use of non-Metasul heads with the Inter-Op Metasul Insert may lead to poor implant performance, increased wear rates, increased metallic debris and failure of the device.

C. Postoperative

Postoperative care is important. The patient should be instructed on the limitations of this device and should be cautioned regarding the load-bearing, range of motion, and activity levels permissible. Early load-bearing should be carefully controlled.

1. Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation or thromboembolism.

2. Postoperative therapies, patient handling, (e.g., changing dressings, placing on bedpans, etc.) and patient activities should be structured to prevent excessive loading of the operative hip. Surgical procedure chosen, patient's age and/or bone quality may necessitate extending the period of limited weight bearing.

3. Periodic X-rays are recommended for close comparison with immediate postoperative X-rays to detect long-term evidence of progressive changes in implant position or loosening. X-rays may also detect evidence of bending, cracking and/or disassembly of components or cement.

4. The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

D. Adverse Effects

The potential adverse effects of the Inter-Op Metasul Acetabular Insert are similar to those occurring with any total hip replacement. These effects are often attributable to factors listed under "Warnings and Precautions" and commonly include:

1. Changing position of the prosthesis (bending, fracture and/or disassembly of components) with or without clinical symptoms.
2. Loosening.
3. Increased metal ions and/or metal debris.
4. Excessive wear of the acetabular component from damage to mating wear surfaces or debris particles.
5. Tissue reactions and allergy to corrosion or wear products (e.g., polyethylene, metal debris, cement debris).
6. Perforation, fissure, fracture of the acetabulum.
7. Subluxation, dislocation, decreased range of motion, and shortening or lengthening of the extremity.
8. Early or late infection.
9. Cardiovascular disorders including damage to blood vessels (iliac, obturator and femoral artery), wound hematoma, venous thrombosis, pulmonary embolism, and myocardial infarction.
10. Temporary or permanent neuropathies, including femoral, sciatic, peroneal, or obturator.
11. Pulmonary disorders including pneumonia and atelectasis.
12. Aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, femoral medialization, or muscular deficiencies.
13. Urological complications, especially urinary retention and infection.
14. Ectopic ossification.
15. Other complications associated with general surgery, drugs, or ancillary devices used, blood, etc.

Storage, Care and Handling

Implants should be stored unopened in their respective trays. Prior to use, inspect packages for punctures or other damage. Protect the prosthesis, particularly mating surfaces, from contact with objects that may damage the surface finish. Visually inspect each implant prior to use for damage.

Sterilization

Unless otherwise indicated, all components have been sterilized by a minimum of 25 kGy (2.5 Mrads) of gamma irradiation and are supplied packaged in protective trays. Inspect packages for punctures and other damage prior to surgery.

RESTERILIZATION OF IMPLANTABLE MEDICAL DEVICES IS NOT RECOMMENDED.

DO NOT RESTERILIZE ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE COMPONENTS BY AUTOCLAVING.

Additional information regarding the Inter-Op Metasul Acetabular Insert may be obtained from Sulzer Orthopedics Inc

Sulzer Orthopedics

Converge Porous Acetabular System

The Converge Porous Acetabular System is compatible with existing Inter-Op Acetabular System inserts and instruments.

Standard Instrumentation

Catalog Number	Description
9200-01-003	Universal Detachable Zimmer Fitting (2 per case)
9200-01-004	Universal Detachable Hudson Fitting
9200-01-203	Universal Acetabular Grater Replacement Sleeve
9200-01-205	Universal Acetabular Grater Handle (2 per case)
9200-02-037/080	Universal Acetabular Grater - Size 37mm - 80 mm
9306-00-003	Acetabular Impactor/Extractor
9306-01-003	Alignment Rod (3/16")
9326-00-103	Universal Extractor Slaphammer
9340-00-000	Universal Impactor Handle
9360-00-038/080	Inter-Op Acetabular System Shell Trial - Size 38mm Through 80 mm
9360-99-100	Acetabular Shell Trial Case
9360-99-101	Acetabular Shell Trial Tray #1
9362-22-039/065	Inter-Op Standard Trial Insert - Size 22mm/39mm - 65 mm
9362-26-049/065	Inter-Op Standard Trial Insert - Size 26mm/49mm - 65 mm
9362-28-045/081	Inter-Op Standard Trial Insert - Size 28mm/45mm - 81 mm
9362-32-049/081	Inter-Op Standard Trial Insert - Size 38mm/55mm - 81 mm
9362-38-055/081	Inter-Op Standard Trial Insert - Size 32mm/49mm - 81 mm
9362-44-061/081	Inter-Op Standard Trial Insert - Size 44mm/61mm - 81mm
9362-99-120	Inter-Op Acetabular System 22 & 26mm Trial Instrument Case
9362-99-121	Inter-Op Acetabular System 22mm Standard & Hooded Trial Insert Tray #1
9362-99-122	Inter-Op Acetabular System 26mm Standard & Hooded Trial Insert Tray #2
9362-99-141	Inter-Op 44mm Trial Insert Tray
9363-22-039/065	Inter-Op Acetabular System Hooded Trial Insert - Size 22mm/39mm - 65 mm
9363-26-049/065	Inter-Op Acetabular System Hooded Trial Insert - Size 26mm/49mm - 65 mm
9363-28-045/081	Inter-Op Acetabular System Hooded Trial Insert - Size 28mm/45mm - 81 mm
9363-32-049/081	Inter-Op Acetabular System Hooded Trial Insert - Size 32mm/49mm -81 mm
9363-99-130	Inter-Op Acetabular System 28mm Standard & Hooded Trial Insert Case
9363-99-131	Acetabular 28mm Standard Trial Insert Tray #1
9363-99-132	Acetabular 28mm Hooded Trial Insert Tray #2
9364-28-051/081	Inter-Op Acetabular System Protrusio Trial Insert - Size 28mm/51mm - 81 mm
9364-32-055/081	Inter-Op Acetabular System Protursio Trial Insert - Size 32mm/55mm - 81 mm
9364-99-140	Inter-Op Acetabular System 28mm & 32mm Protrusio Trial Insert Case
9364-99-141	Acetabular 28mm Protrusio Trial Insert Tray #1
9364-99-142	Acetabular 32mm Protrusio Trial Insert Tray #2
9365-99-150	Inter-Op Acetabular System Aligner/Impactor Case
9365-99-151	Acetabular Aligner Tray #1
9365-99-152	Acetabular Impactor/Misc. Comp. Tray #2
9365-99-153	Acetabular Universal Trial Tray sizes 39-71mm (any style or ID)
9366-00-006	Inter-Op Acetabular System Shell Impactor/Extractor/Aligner/Positioner
9366-00-010	Inter-Op Threaded Straight Shell Impactor Rod (2 per case)
9366-00-015	Straight Hex Head Screwdriver
9366-00-016	Universal Joint Hex Head Screwdriver
9366-00-017	Universal Joint Hex Head Shaft
9366-00-040	Flexible Depth Gauge
9366-00-041	Inter-Op Acetabular System Drill Bit Size - 3.2mm/35mm
9366-00-042	Inter-Op Acetabular System Drill Bit Size - 3.2mm/50mm
9366-00-043	Inter-Op Acetabular System Drill Bit Size - 4.5mm/35mm
9366-00-044	Inter-Op Acetabular System Drill Bit Size - 4.5mm/50mm
9366-00-050	Acetabular Drill Guide 3.2mm
9366-00-051	Acetabular Drill Guide 4.5mm
9366-00-060	Fixed Angle Driver
9366-00-061	3.5 x 16.5mm Hex Bit
Catalog Number	Description
9366-00-062	Tap - Cancellous Screw
9366-00-063	Inter-Op Acetabular Insert Extractor
9366-00-064	Straight Ratchet Handle
9366-00-065	1/4" Square Drive to AO Adapter (Req w/Ratchet Handle)
9366-00-066	Flexible Driver (2 Per Case)
9366-00-067	Revision T-handle
9366-00-070	Screw Hole Seal Extractor Inter-Op Acetabular System
9366-00-080	Trial Insert Captured Screw (Replacement)
9366-22-000	Inter-Op Acetabular System 22mm Insert I.D. Impactor
9366-22-008	Inter-Op Acetabular System 22mm Insert Rim Impactor
9366-26-001	Inter-Op Acetabular System 26mm Insert I.D. Impactor
9366-26-009	Inter-Op Acetabular System 26mm Insert Rim Impactor
9366-28-002	Inter-Op Acetabular System 28mm Insert I.D. Impactor
9366-28-010	Inter-Op Acetabular System 28mm Insert Rim Impactor
9366-28-012	Inter-Op Acetabular System 28mm Insert Rim Impactor <49
9366-32-003	Inter-Op Acetabular System 32mm Insert I.D. Impactor
9366-32-011	Inter-Op Acetabular System 32mm Insert Rim Impactor
9366-32-013	Inter-Op Acetabular System 32mm Insert Rim Impactor <55
9366-38-004	Inter-Op Acetabular System 38mm Insert I.D. Impactor
9366-38-014	Inter-Op Acetabular System 38mm Insert Rim Impactor
9366-44-004	Inter-Op Acetabular System 44mm Insert ID Impactor
9366-44-014	Inter-Op Acetabular System 44mm Insert Rim Impactor
9666-44-000	Head Trial size 44mm/neutral (12/14 Taper)
9666-44-004	Head Trial size 44mm/-4mm (12/14 Taper)
9666-44-008	Head Trial size 44mm/-8mm (12/14 Taper)
9666-44-400	Head Trial size 44mm/+4mm (12/14 Taper)
9666-44-800	Head Trial size 44mm/+8mm (12/14 Taper)
9366-99-160	Acetabular Screw Instrument Case
9366-99-161	Acetabular Screw Instrument Tray #1
9367-99-170	Acetabular Acetabular Grater Case
9367-99-171	Acetabular Acetabular Grater Tray #1
9367-99-172	Acetabular Acetabular Grater Tray #2
9367-99-180	Acetabular Miscellaneous Trials Case
9400-00-100	Universal Snake Acetabular Retractor

Femoral Heads

Catalog Number	Description
7210-22-000	12/14 Taper CoCr Head - Size 22/Neutral Neck
7210-22-350	12/14 Taper CoCr Head - Size 22/+3.5mm Neck
7210-22-800	12/14 Taper CoCr Head - Size 22/+8mm Neck
7210-28-000	12/14 Taper CoCr Head - Size 28/Neutral Neck
7210-28-004	12/14 Taper CoCr Head - Size 28/-4mm Neck
7210-28-400	12/14 Taper CoCr Head - Size 28/+4mm Neck
7210-28-800	12/14 Taper CoCr Head - Size 28/+8mm Neck
7210-32-000	12/14 Taper CoCr Head - Size 32/Neutral Neck
7210-32-004	12/14 Taper CoCr Head - Size 32/-4mm Neck
7210-32-400	12/14 Taper CoCr Head - Size 32/+4mm Neck
7210-32-800	12/14 Taper CoCr Head - Size 32/+8mm Neck
01.01012.384	12/14 Taper CoCr Head - Size 38mm/-4mm Neck
01.01012.385	12/14 Taper CoCr Head - Size 38mm/-4mm Neck
01.01012.386	12/14 Taper CoCr Head - Size 38mm/Neutral Neck
01.01012.387	12/14 Taper CoCr Head - Size 38mm/+4mm Neck
01.01012.388	12/14 Taper CoCr Head - Size 38mm/+8mm Neck
01.01012.444	12/14 Taper CoCr Head - Size 44mm/-8mm Neck
01.01012.445	12/14 Taper CoCr Head - Size 44mm/-4mm Neck
01.01012.446	12/14 Taper CoCr Head - Size 44mm/Neutral Neck
01.01012.447	12/14 Taper CoCr Head - Size 44mm/+4mm Neck
01.01012.448	12/14 Taper CoCr Head - Size 44mm/+8mm Neck

Durasul Components

Catalog Number	Description
4376-22-039/047	Inter-Op Durasul Standard Insert size 22mm x 39mm - 47mm
4376-28-045/081	Inter-Op Durasul Standard Insert size 28mm x 45mm - 81mm
4376-32-049/081	Inter-Op Durasul Standard Insert size 32mm x 49mm - 81mm
4376-38-055/081	Inter-Op Durasul Standard Insert size 38mm x 55mm - 81mm
4376-44-061	Inter-Op Durasul StandardInsert size 44mm x 61mm - 81mm
4377-22-039/047	Inter-Op Durasul Hooded Insert size 22mm x 39mm - 47mm
4377-28-045/081	Inter-Op Durasul Hooded Insert size 28mm x 45mm - 81mm
4377-32-049/081	Inter-Op Durasul Hooded Insert size 32mm x 49mm - 81mm

Conventional PE Inserts

Catalog Number	Description
4364-22-039/065	Inter-Op Standard Insert size 22mm x 39mm - 65mm
4364-26-049/065	Inter-Op Standard Insert size 26mm x 49mm - 65mm
4364-28-049/081	Inter-Op Standard Insert size 28mm x 49mm - 81mm
4364-32-055/081	Inter-Op Standard Insert size 32mm x 55mm - 81mm
4365-22-039/065	Inter-Op Hooded Insert size 22mm x 39mm - 65mm
4365-26-049/065	Inter-Op Hooded Insert size 26mm x 49mm - 65mm
4365-28-049/081	Inter-Op Hooded Insert size 28mm x 49mm - 81mm
4365-32-055/081	Inter-Op Hooded Insert size 32mm x 55mm - 81mm
4366-28-049/081	Inter-Op Protrusio Insert size 28mm x 55mm - 81mm
4366-32-055/081	Inter-Op Protrusio Insert size 32mm x 55mm - 81mm

Sulzer Orthopedics

Converge Porous Acetabular System

Metasul Components

Catalog Number	Description
4372-28-049/081	Inter-Op Metasul Standard Insert Size 28mm/49mm -81mm
7340-28-000	Metasul CoCr Head, 12/14 Taper, Size 28 mm/neutral
7340-28-004	Metasul CoCr Head, 12/14 Taper, Size 28 mm/-4mm
7340-28-400	Metasul CoCr Head, 12/14 Taper, Size 28 mm/+4mm
7340-28-800	Metasul CoCr Head, 12/14 Taper, Size 28 mm/+8mm

Metasul Instrumentation

Catalog Number	Description
In addition to the standard instrumentation, Metasul requires the following instruments:	
9340-00-002	Metasul Insert Impactor
9366-11-063	Metasul Insert Extractor

Converge Porous Acetabular System

Catalog Number	Description
6360-00-039/065	Converge Hemispherical Porous Shell size 39mm-65mm
6361-00-039/065	Converge Rim Flare Porous Shell size 39mm-65mm
5361-00-039/071	Converge Rim Flare w/Screwholes Porous Shell size 39mm-71mm
5360-00-039/071	Converge Cluster-Hole Porous Shell size 39mm-71mm
5362-00-053/081	Converge Multi-Hole Porous Shell size 43mm-81mm
5363-00-053/081	Converge Protrusio Porous Shell size 53mm-81mm

X-Ray Templates

Catalog Number	Description
1000-55-560	Converge Hemispherical/Cluster-Hole Porous Shell with sealed screwholes size 39mm-71mm
1000-55-561	Converge Rim Flare Porous Shell size 39mm-71mm
1000-55-562	Converge Multi-Hole and Protrusio Porous Shell with sealable screwholes size 43mm-81mm

Sales Aids

Catalog Number	Description
1001-45-011	Technical Brochure on Hemispherical and Rim flare shells

Sulzer Orthopedics

Innovators in Medical Device Technology

Knees

Apollo® Knee System
Classic condylar knee replacement system.

MOST™ System
Modular knee and hip options for severe bone loss and trauma.

Natural-Knee® System
Anatomic design for superior clinical results.

Hips

Alloclassic™ Hip
Classic proven design with superior clinical results.

Allofit™ Acetabular Cup System
Unique ridgelock surface designed for easy implantation and stability.

Apollo® Hip System
Designed for optimal results with low-demand patients.

APR® Anatomical Hip System
Anatomically designed hip replacement system.

Converge™ Porous Acetabular System
Where technology and experience meet.

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Highly crosslinked polyethylene without measurable wear.

FracSure™ Hip System
A classic design for hip fractures.

Metasul® Metal-on-Metal Acetabular Components
Backed by a limited Lifetime Warranty and over 10 years clinical results.

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A highly polished cemented stem.

Natural-Hip™ System
A complete, state-of-the-art hip system.

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A better solution for revision hips.

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A stable revision design with extensive sizes.

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Infinite adjustments of inclination & retroversion for precisely restored anatomy.

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A nonconstrained design with 21 years of clinical results.

Select® Shoulder System
TSA and fracture management with offset head options.

SULZER*MEDICA*
Sulzer Orthopedics Inc.
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Austin, Texas 78717

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877.768.7349
fax: 512.432.9014

Metasul acetabular components must be used only with Metasul femoral heads and Sulzer Orthopedics femoral components. Members of the medical profession should determine the appropriateness of the surgical procedures and techniques herein based upon his/her own medical training, knowledge and experience.

Products are distributed in Europe by Sulzer Orthopedics Ltd., Grabenstrasse 25, CH-6341, Baar, Switzerland, 011 (41) 41-768-3232; in Canada by Sulzer Orthopedics Canada, Inc., 265 Bartley Drive, Toronto, Ontario, Canada M4A2N7, (416) 751-8787; in Australia by Sulzer Australia Medical, Level 5, 384 Eastern Valley Way, Chatswood, NSW 2067, Australia, 011 61 2 9417 7922; and in Japan by Sulzermedica Japan K.K., Itopia Eitai Bldg., 7F 1-3-7, Saga, Koto-Ku, Tokyo 135-0031, Japan, 011 81 3 3820 7477.

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